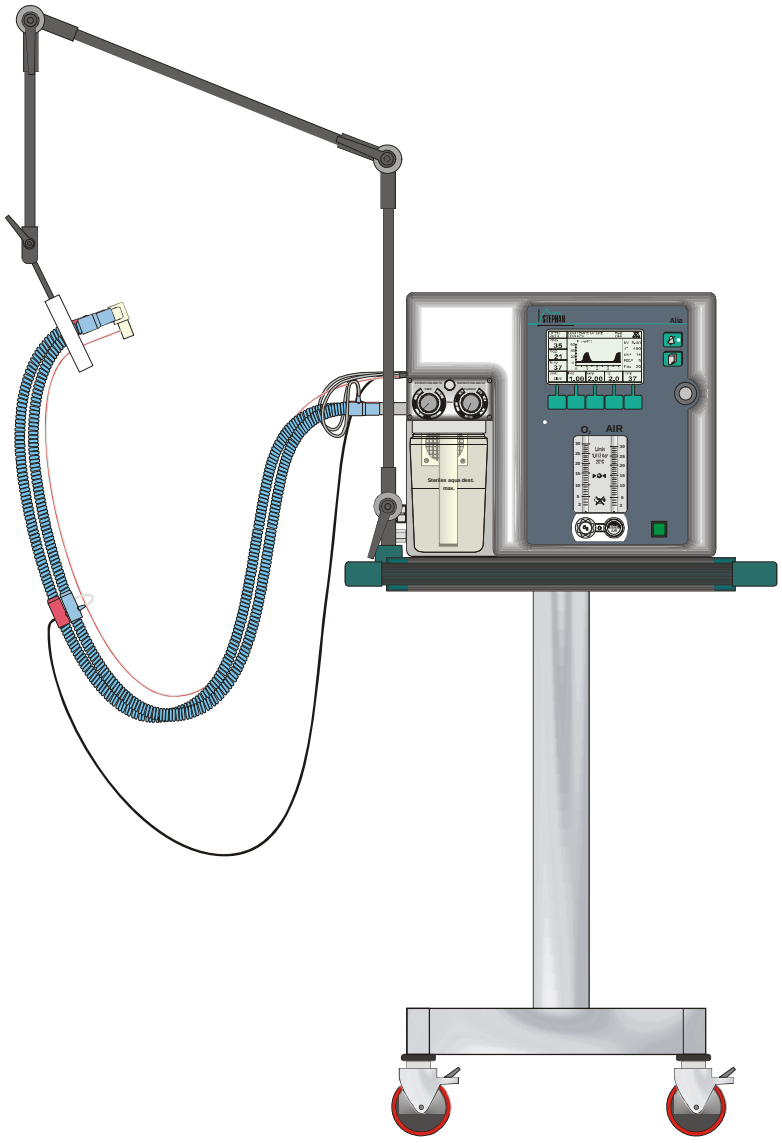
STEPHAN

Clinical Experience
Technical Competence

Alia

Ventilator



Service Instructions

CE 0482

Service instructions

These service instructions aim to provide assistance for troubleshooting activities with the **ALIA** ventilator.

It contains drawings, circuit diagrams and parts lists for a better understanding of how the ventilator works.

Service and maintenance work can be carried out to the peripheral components of the **ALIA** ventilator. Repairs to the electronic control of the ventilator can only be carried out by F. STEPHAN GMBH or authorized service partners. Otherwise the entire electronic systems in the **ALIA** ventilator require no maintenance.

Every step of a specific procedure should be read through carefully before starting to service the unit. Always only use the correct tools and the stated measuring equipment. Failure to follow the instructions and/or recommendations in these service instructions can result in the device not working properly or cause damage to the device.

Only use original spare parts by F. STEPHAN GMBH as contained in the spare parts list (see chapter 10 p. 75).

Note

These service instructions do not replace the operating instructions. Handling the device in any way presumes an exact knowledge and compliance with the operating instructions. The device is only intended for the described purpose.

F. Stephan GmbH
- Medizintechnik -
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Subject to technical alterations.

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1 General information

1.1 Device name and manufacturer

Device name **ALIA**

Manufacturer

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1.2 Maintenance and repairs

In the interests of device safety, maintenance of the **ALIA** ventilator should be carried out every six months.

Safety checks must be carried out every six months.

Maintenance must be carried out by the authorized customer service of F. STEPHAN GMBH.

Only spare parts from F. STEPHAN GMBH must be used during maintenance.

Caution!

Clean and disinfect the device respectively device parts every time before maintenance, even when returning the device for repairs.

1.3 Abbreviations and definitions

Abbreviation	Definition	Meaning
%h	Percentage hours	Service life of the oxygen sensor in hours depending on the oxygen concentration
AIR		Medical compressed air
aqua dest.	Aqua destilata (lat.)	Distilled, demineralized water
bar		Unit of measurement for compressed air
Batt	Rechargeable battery	Device for storing electrical energy in the form of chemical energy
cmH_2O		Unit of measurement for compressed air = mbar
FiO_2		Inspired oxygen concentration
IGR	Incremental transducer	Push button and knob
PDU	Power distribution unit	Power Distribution Unit
PEEP	Positive end expiratory pressure	
V	Volt	Unit of measurement for electrical voltage

Table 1: Abbreviations and definitions

 © F. Stephan GmbH

1.4 Safety instructions

Refers to instructions drawing attention to important facts.

The following safety instructions appear at relevant points in the service instructions and must always be heeded.

Warning

Refers to warnings which, if not heeded, can result in malfunctions, damage or defects in the device, which can possibly also put the patient at danger.

Caution

Refers to precautions which, if not heeded, can result in damage to the device and its accessories.

2 Mechanical structure

The **ALIA** ventilator consists of a basic housing and a front housing. The front housing also acts as the device cover.

Fig. 1: Basic and front housing: general

Front housing

Remove the front housing to open the **ALIA** ventilator.

Warning

Risk of an electric shock

Disconnect from the power source before opening the housing!

The front housing is screwed to the frame with 15 countersunk screws M4x10. The 9 screws used on the side of the device are also fitted with rosettes to prevent damage to the plastic front housing when tightening the screws.

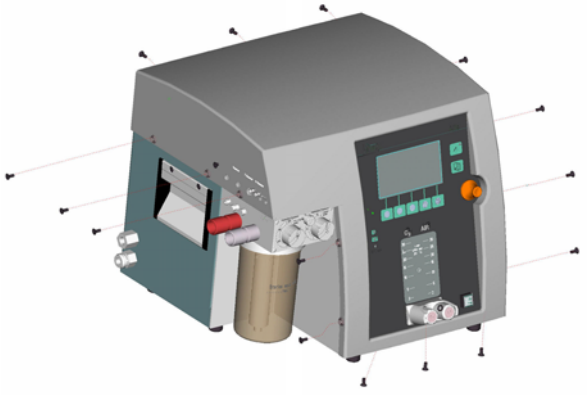

Fig. 1: Opening the housing

The front housing can now be hinged open to the front.

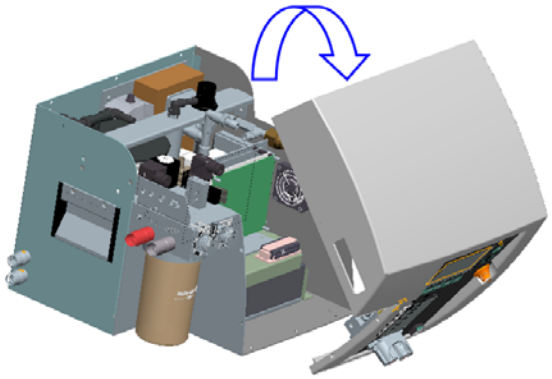

Fig. 2: Hinging open the housing

Before hinging open the front housing, ensure that the connectors for the tube heating, the temperature sensors and the pneumotachograph have been disconnected.

The plastic front housing is coated with an EMC varnish on the inside. It contains the input periphery of the **ALIA** ventilator.

This input periphery consists of touch buttons, the IGR (push/turn knob), the LCD display, the controller board, the double flowmeter ON/OFF switch on the front pane.

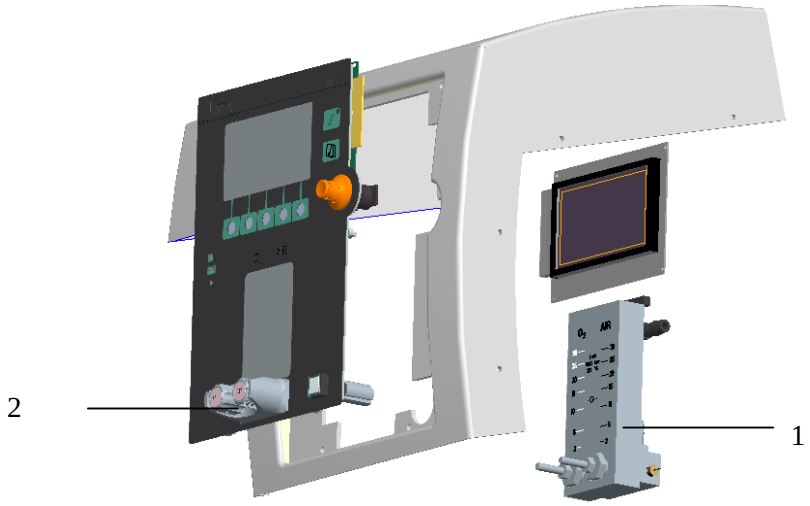

Fig. 3: Front housing with input periphery

1 double flow meter

2 FiO_2 and flow adjustment

Basic housing

The frame of the **ALIA** ventilator and its reinforcement bar, fastening bracket and panels consist of 2 mm thick powder-coated aluminium. The bottom of the housing has a cut-out for the rechargeable battery.

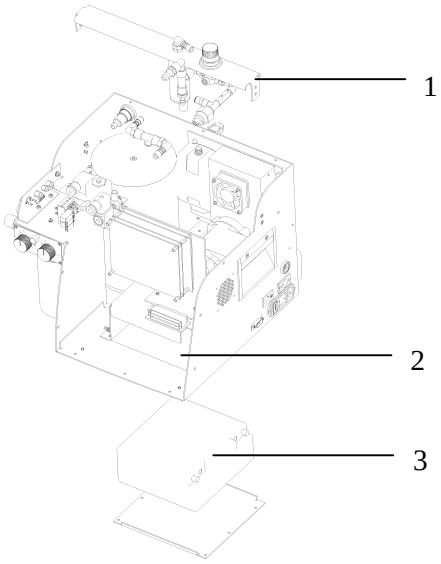

Fig. 4: Basic housing

1 Reinforcement bar
2 Cut-out for rechargeable battery
3 Rechargeable battery

Service flap

The intake filter and oxygen sensor are located behind a service flap on the back of the ventilator.

To open the service flap, loosen the knurled screws by turning counter-clockwise.

The oxygen sensor is located on the left next to the intake filter. It is screwed into the connection block.

It can be removed by turning counter-clockwise.

The electrical connection between the oxygen sensor and device consists of a 2-pin AMP connector.

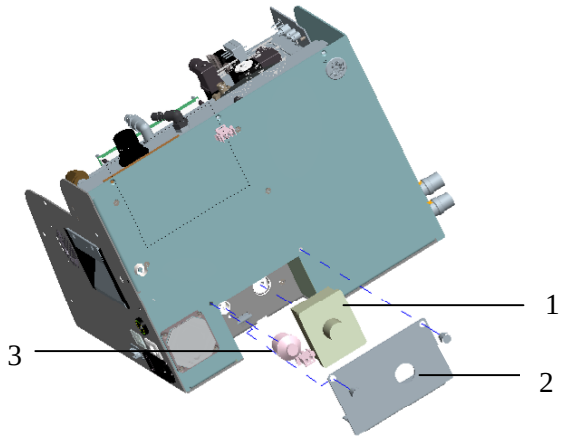

Fig. 5: Service flap

1 Intake filter
2 Service flap
3 Oxygen sensor

On the left and right side wall there are recessed handles for carrying the **ALIA** ventilator.

Some of the electronic controls and the power supply are accommodated inside the ventilator.

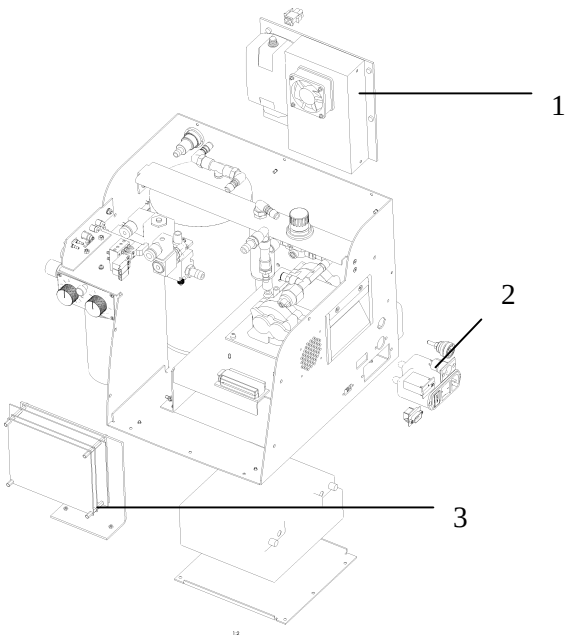

Fig. 6: Electronic components

1 Power supply
2 Cold device connector combination
3 Electronic controls

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The entire pneumatic system is accommodated in the basic housing. Only the double flowmeter is in the front housing.

The pneumatic system consists of the compressor, the fresh gas reservoir and its control valves. The pressure switches for detecting the intake pressure are firmly integrated in the pneumatic system

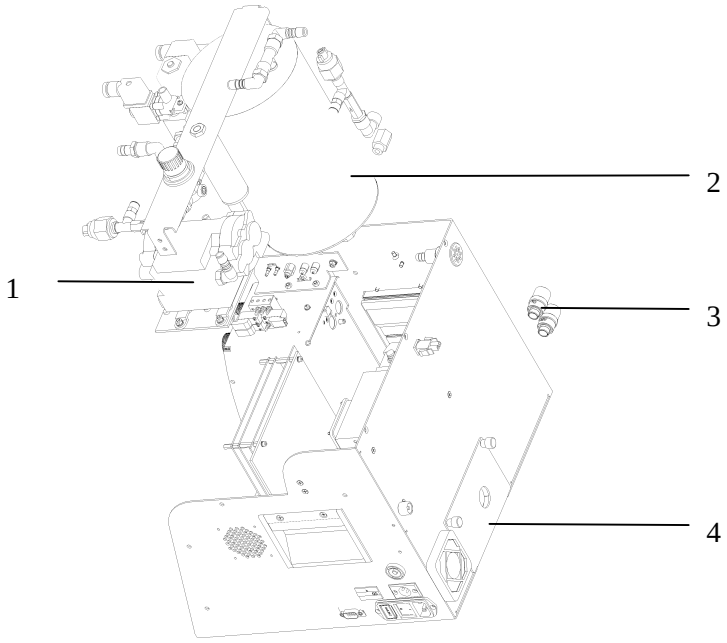

Fig. 7: pneumatic components

1	compressor	2	fresh gas reservoir
3	gas inlets	4	service flap

The patient part is connected to the basic device from the front.

The patient part is held in position by the guide rail.

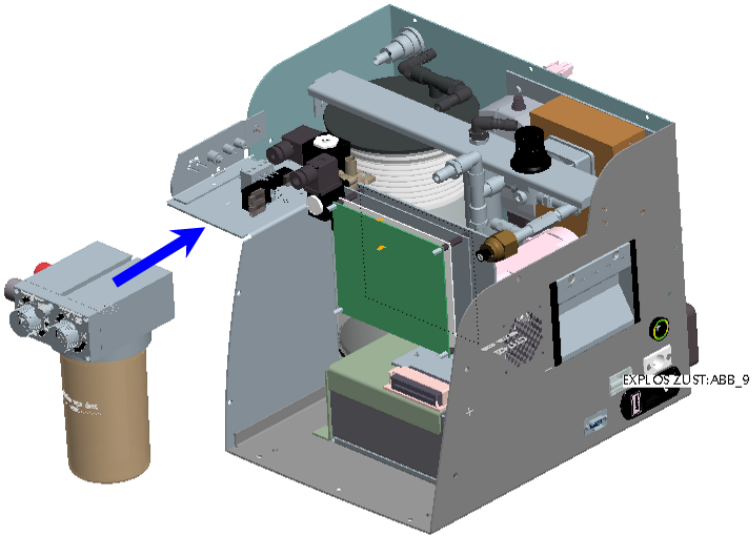

Fig. 8: Inserting the patient part

3 Components and functions

The **ALIA** ventilator consists primarily of the following parts:

- Electronic controls
- Power supply
- Gas supply
- Fresh gas reservoir
- Patient part
- Patient tube system

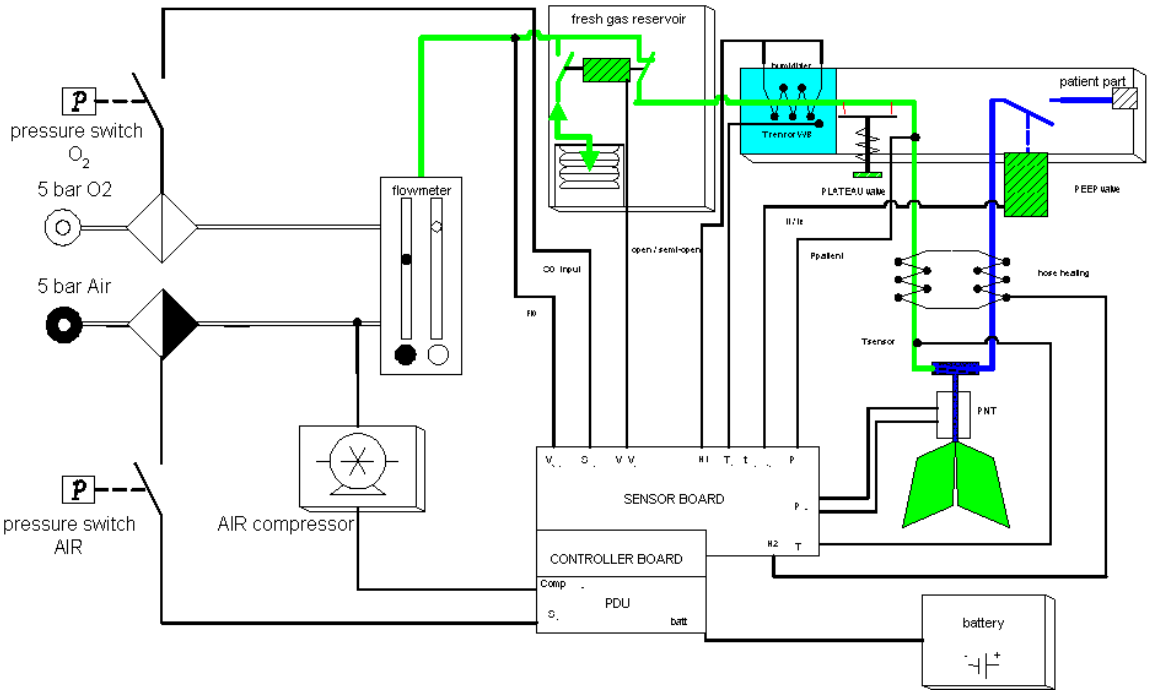

Fig. 9: **ALIA** block diagram

3.1 Electronic controls

The **ALIA** ventilator uses an 8-bit micro controller. This controls the sensors and actuators in the system.

In addition to these components, the unit also has electronic components which provide the electrical power supply.

These consist of a power supply unit and a device for bridging any power failure. In the event of a power failure, the device switches over to battery operation and regulates the battery charging process.

The sensor board generates voltages of ±15V and -5V, and the controller board generates + 5V.

3.1.1 Sensor board

The sensor board acts as interface for triggering the actuators (control of the fresh gas reservoir and the expiration valve) and for registering the measured data (pressure and differential pressure sensors, AD converter).

An SPI bus system provides the link to the micro controller. This simplifies linking the various components in terms of both hardware and software.

The following illustration shows the components on the sensor board.

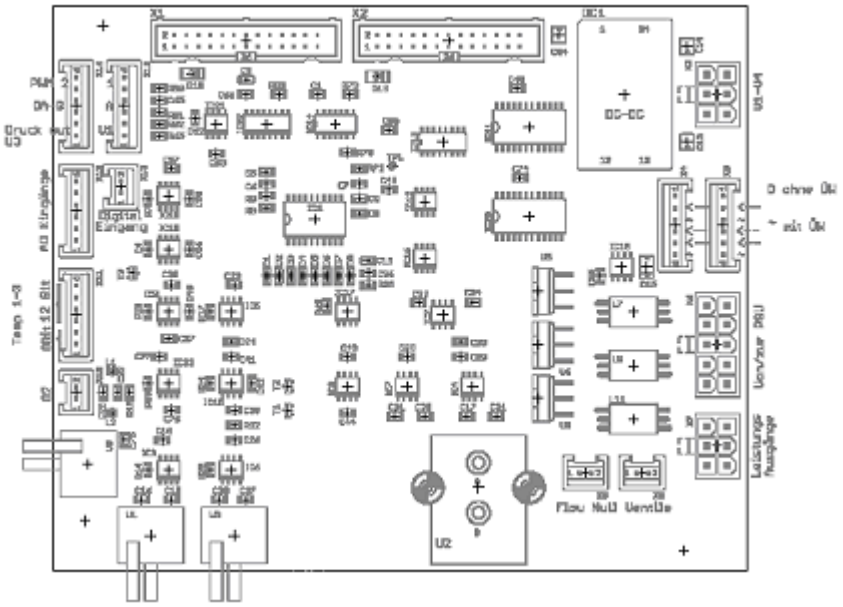

Abb. 2: Sensor board

Main task

The main task of the sensor board is to convert the analog signals.

Voltage signals (input):

Rechargeable battery voltage
"DC_good" signal
On/off signal
Input voltage
12 V (for heating and valves)
Inspired pressure
Expired pressure
Flow sensor differential pressure
Oxygen sensor cell voltage

Voltage signals (output):

Heating
Valves
"Batt_enable"

The power supply for the electronic components is generated by a DC/DC converter on the sensor board, generating +15V, -5V and -15V.

The input signals for On/Off, DC_good, input voltage and "Batt_enable" are sent to the SPI bus by a slide register. The input signals for pressure, flow, O_2 and battery voltage are sent to the SPI bus following amplification and conversion via an 8-channel AD/12 bit converter.

The AD converter is equipped with protective diodes (max. 5V) on the input side.

A serial chargeable slide register with power amplifier is used for triggering the heating and the valves, via the SPI bus.

Pressure sensors

The respiratory pressure is measured at the inspiration fitting of the patient part. The pressure present here is conveyed via a tube to the pressure sensors (respiratory pressure).

For safety reasons, two pressure sensors are provided for measuring the respiratory pressure.

The differential pressure developing over the resistance body of the PNT head is used for measurement of the volume flow. This differential pressure is conveyed via two tubes to the differential pressure sensor.

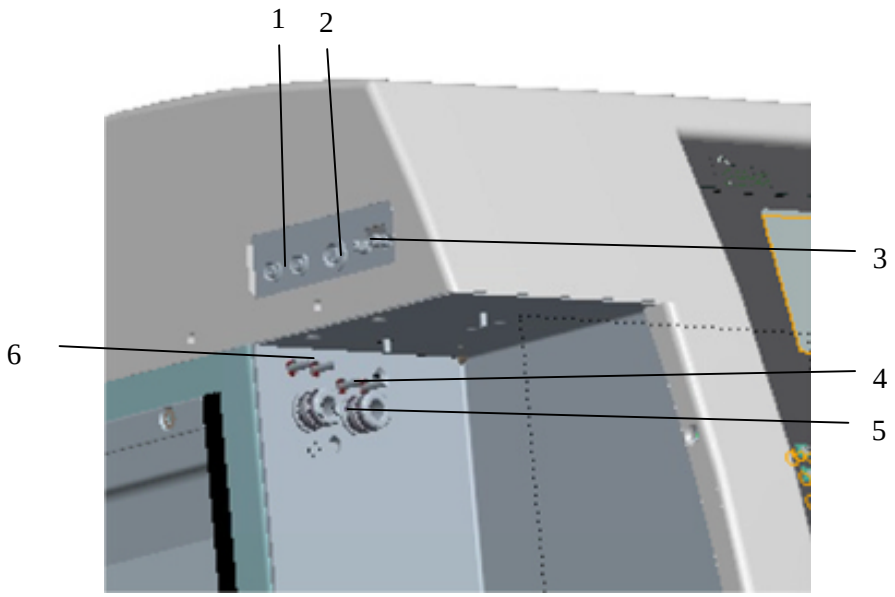

Fig. 10: PNT and pressure fitting

1 hose heating socket
2 temperature sensor socket
3 pneumotachograph connector
4 electrical connection magnetic coil
5 pressure fittings
6 water bath connectors

Calibration block

The calibration block allows for offset calibration of the differential pressure sensor and the oxygen sensor.

The interposed solenoids V4 and V5 switch the measuring lines of the differential pressure sensor against the atmosphere. The valves are switched at exactly the same time. The value measured in this way corresponds to a flow of 0 l/min.

FiO_2 measurement

FiO_2 measurement is carried out using an electrochemical cell (fuel cell). This oxygen sensor generates a voltage depending on the prevailing oxygen concentration. The voltage is then converted electronically into a corresponding signal.

To calibrate the oxygen sensor, compressed air (21% O_2) is blown against it via solenoid V6. During this procedure, the display shows "CAL" in the window of the FiO_2 value. After completing calibration, the valve switches the oxygen sensor back to the output of the double flowmeter.

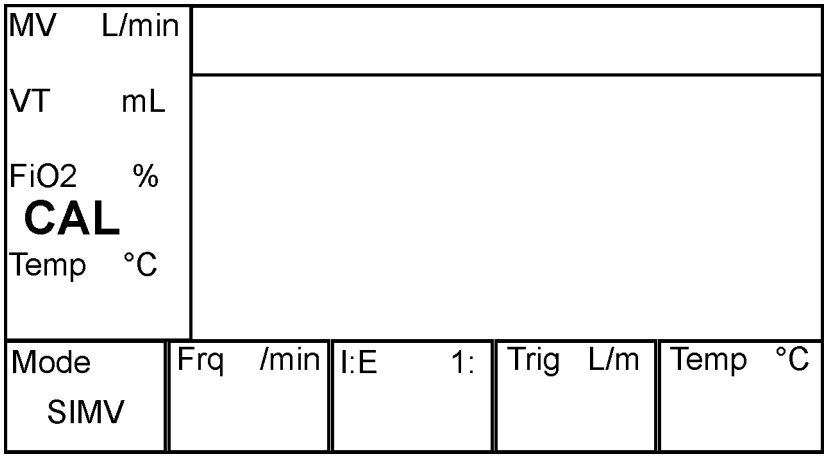

Fig. 11: Display showing 'CAL'

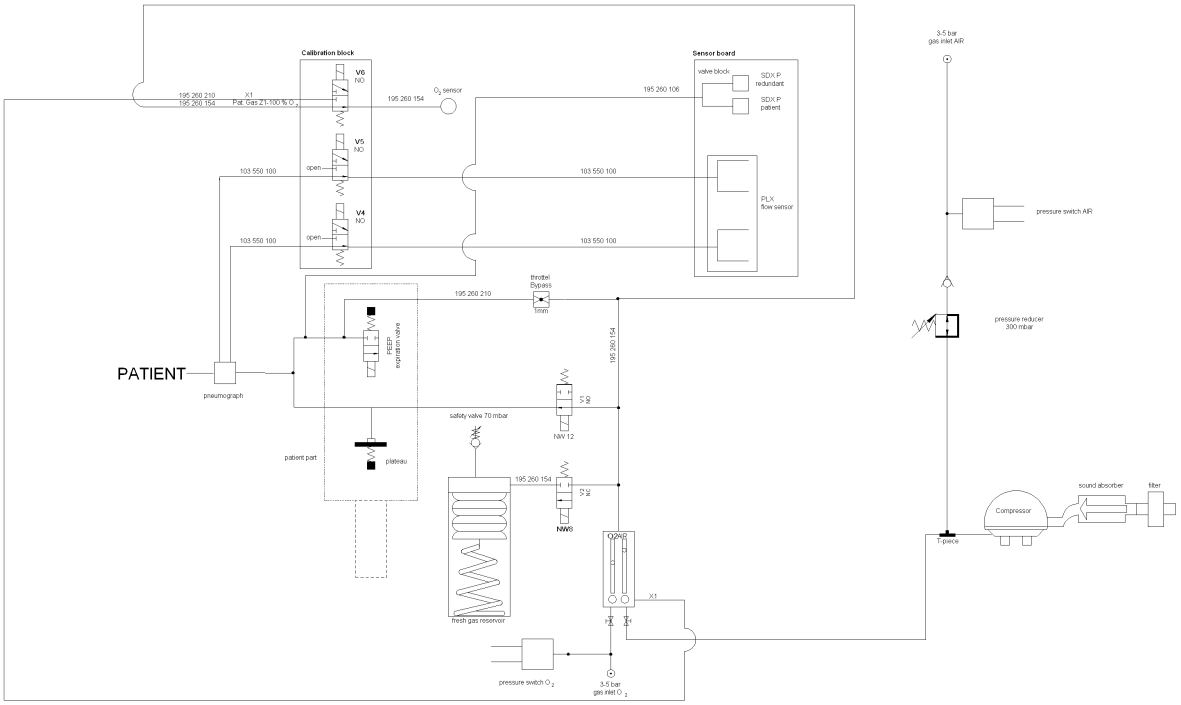

Fig. 12: Pneumatic function diagram

3.1.2 Controller board

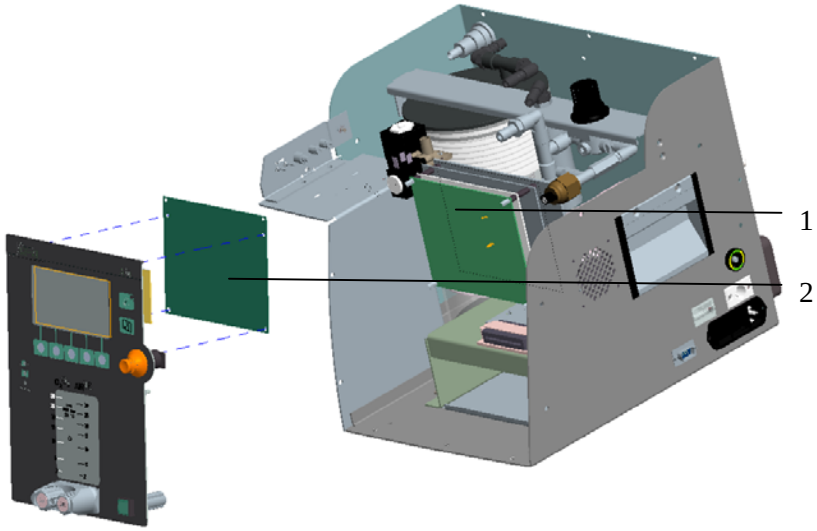

Fig. 13: Controller board

1	PDU board	2	controller board

Various functional groups are accommodated on the controller board.

The figure shows the functional groups for the user interface, CPU and interfaces.

The user interface consists of the keyboard, display (LCD) and LEDs as input and output units for regular handling of the system. The controller board also contains the alarm system for indicating alarm statuses.

The digital interfaces for triggering the actuators and reading the sensors (via the sensor board) are integrated on the controller board.

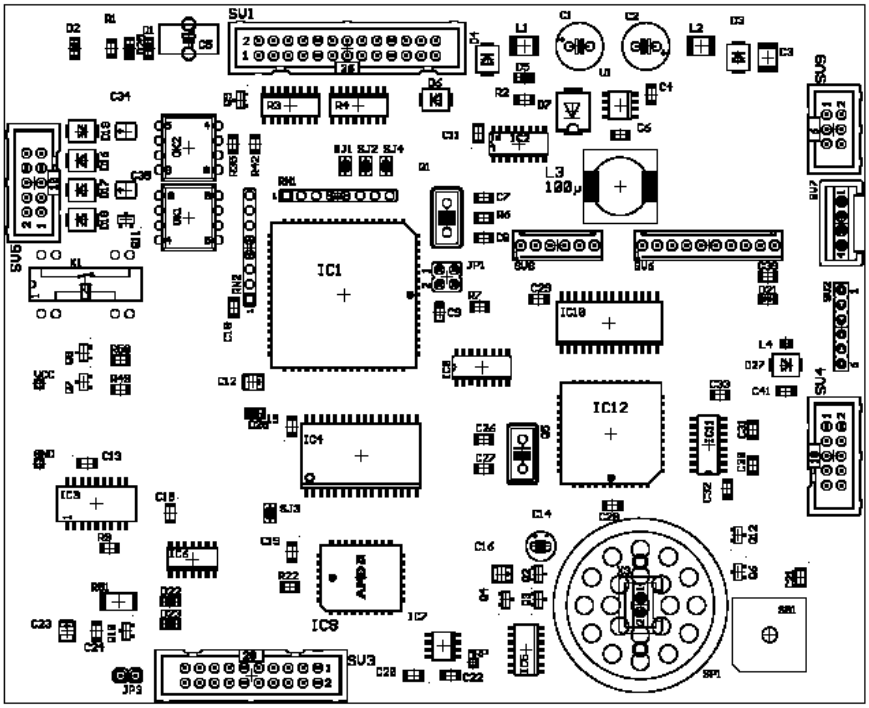

Fig. 14: Controller board

Main task

The main task of the controller board is to proceed with ventilation.

The procedure consists of registering the measured values of the sensor board and calculating the values for output.

If the monitor fails, the limit values are still monitored and acoustic alarms are produced if necessary.

The processor is an M68HC11 with external Flash ROM and RAM. The necessary voltage of +5V is generated on the board itself (switching regulator).

Two acoustic alarms are generated (piezo electric signal transducer, loudspeaker) and two visual alarms.

An RS232 converter with optocoupler for electrical isolation is used for communication with a PC.

The second RS232 converter without electrical isolation is not used on this board.

A further task performed by the controller board is to manage the GUI (graphical user interface).

The signals of the capacitive sensor button on the front panel and of the incremental transducer (IGR) are read and processed by processor M68HC11.

In addition, the graphic output is generated on the LCD.

3.1.3 Power Distribution Unit PDU

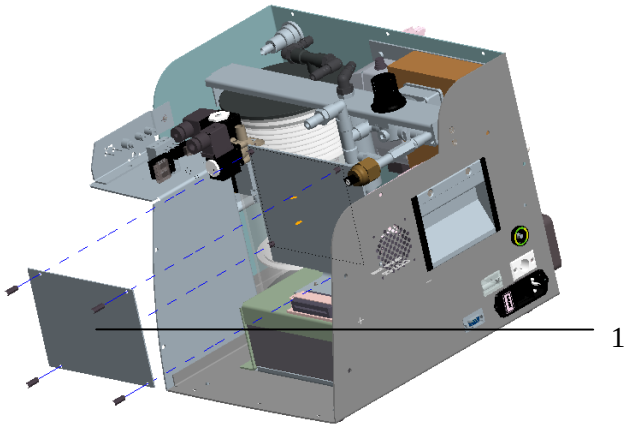

Fig. 15: Power Distribution Unit PDU

1 PDU board

The task of the Power Distribution Unit PDU is to safeguard operating voltage and the constant current charge for the rechargeable battery.

Visual and acoustic alarms are generated for error statuses.

If the output voltage of the power unit is greater than that of the battery, then the **ALIA** ventilator runs completely off mains power.

If the output voltage of the power unit falls below that of the battery (power failure, voltage fluctuations, etc.) then the ventilator runs off the battery. This happens without electronic changeover (parallel mode).

The Power Distribution Unit PDU can only be switched on by a switched on by a rechargeable battery. This can also be discharged (≥ 10.8 V).

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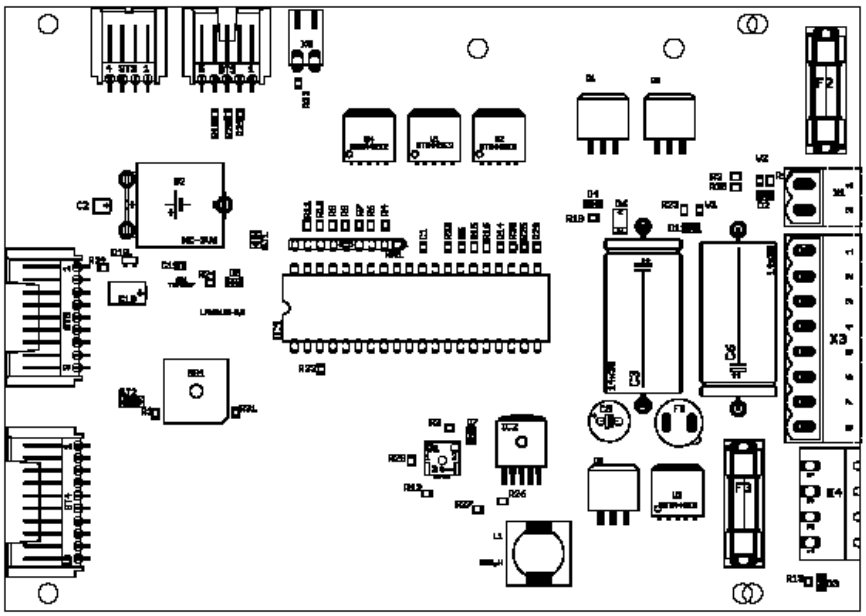

Fig. 16: Power Distribution Unit PDU

Tasks

- Checking input voltage
- Uninterrupted contactless changeover of the power supply sources with consideration of the voltage hysteresis defined by the software
- Recharging the battery
- Battery test under partial load
- Visual LED test when **ALIA** starts up
- Testing the piezo electrical signal transducer when **ALIA** starts up
- Switching the compressor on and off
- Communication with the micro controller
- Checking the external air pressure supply

Voltage changeover

Changeover of the various voltages takes place without any contact.

The current voltage source is indicated by the LEDs on the front of the unit.

The charge status of the battery is shown by three coloured LEDs (red, orange and green).

The charge curve is taken into consideration. The charge status can be read off the LEDS:

- red = 10-40 %
- orange = 40-90 %
- green = 90-100 %

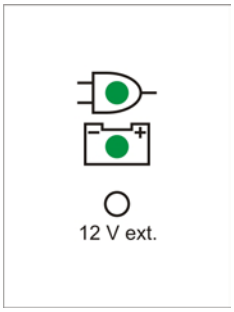

Fig. 17: Battery display

Testing the LEDs and the piezo

Once the ON switch on the front of the unit has been pressed, the system starts with a self-test which shows the user that the control elements are functioning. The self-test consists of the following sequence:

1. green LED of the mains power supply lights up
2. green LED of the 12V vehicle power supply lights up
3. green LED of the battery lights up
4. red LED of the battery lights up
5. piezo sounds
6. everything goes off again

Battery test

The battery test is only carried out when **ALIA** starts up.

The supply voltages are switched off internally for this purpose.

The test is displayed by the red and green LEDs in the battery symbol which flash alternately.

The battery test is carried out with load on the battery by switching the compressor on (approx. 2 amps for 6 s). This starts immediately after the self-test. A brief alarm is given if the system does not pass the battery test.

Total discharge protection for the battery

Total discharge protection comes into force when the measured voltage of the battery is <10.8V (Batt_enable = 0). An acoustic and visual alarm is given.

The user should stop using the ventilator and recharge the battery, or provide another voltage source.

Compressor ON/OFF

The compressor is switched on/off without any contact.

Communication with the micro controller

Communication with the micro controller is limited to the following signals:

- Batt_enable (battery voltage ≥ 10.8V)
- Offreq. (signal of the ON/OFF switch)

External air pressure supply

A pressure switch detects the external air pressure supply.

If the input pressure is < 1 bar, then the internal compressor is automatically switched on.

If the compressor is switched off when using an external air supply, this prolongs the battery mode.

3.2 Power supply

The integrated power supply unit is responsible for connecting the **ALIA** ventilator to the mains power supply.

The cold device connector combination with integrated mains filter supplies power to the power supply unit.

As an alternative to the mains power supply, the **ALIA** can be operated from an external 12V DC voltage source.

If no external voltage source is available, the integrated rechargeable battery is automatically used to supply power to the ventilator. The rechargeable battery provides a backup power supply in the event of a mains power failure.

The Power Distribution Unit controls the changeover to the provided voltage source.

3.2.1 Power supply unit

The **ALIA** ventilator is equipped with a Power supply unit in accordance with DIN EN 60601.

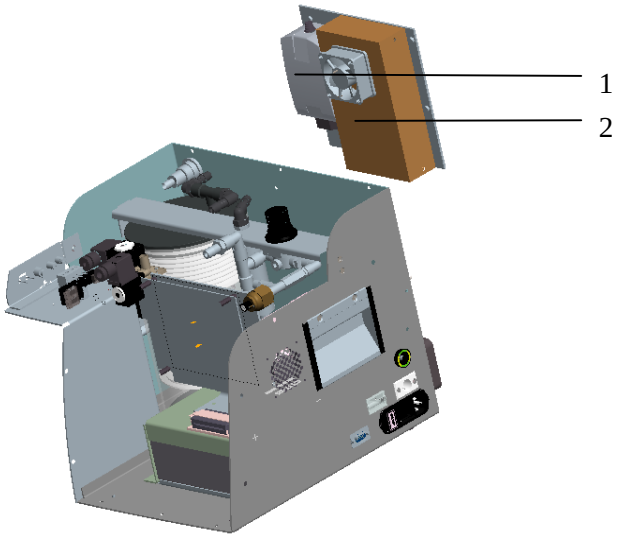

Fig. 18: **ALIA** power supply unit

1 inverter

2 power supply unit

Input voltage:	100 – 240 V AC, 2 A, 50/60 Hz
Fuse:	2 A
Output voltage:	15 V DC, 185 W
Fuse:	16 A

The output voltage of 15V DC and the DC_good signal are conveyed directly to the Power Distribution Unit PDU.

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3.2.2 Rechargeable battery

The integrated rechargeable battery works parallel to the external power supply. That means that the system changes over to battery operation without any interruptions in the event of a mains failure.

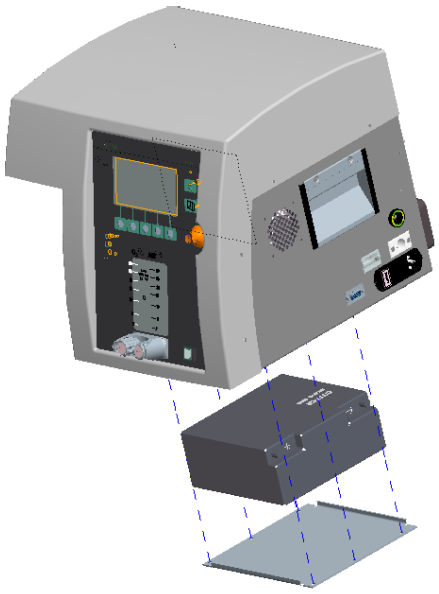

Fig. 19: Rechargeable battery

Battery type:	Gel-type lead battery
Weight:	6.2 kg
Rated voltage:	12 V
Rated capacity:	17 Ah
Fuse:	10 A
Recharging time:	18 h
Operating time:	approx. 1 h with heating
	approx. 3.5 h without heating
Connections:	threaded hole M5

3.2.3 Inverter

The integrated clocked inverter is used only to supply power to the internal compressor for generating compressed air.

The power supply is switched directly from the Power Distribution Unit PDU (compressor ON/OFF).

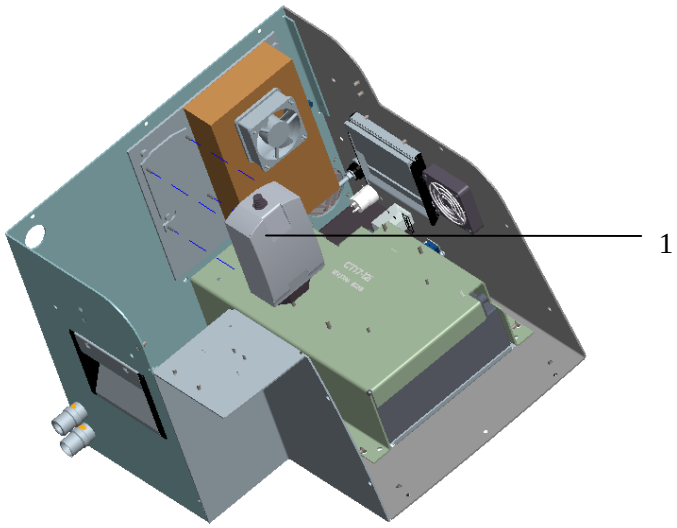

Fig. 20: Inverter

1 inverter

Input voltage :	15V/DC
Output voltage:	230V/AC, 50 Hz stabilized
Continuous power:	100 W

The inverter has thermal overload protection and electronic short-circuit protection.

3.3 Gas supply

The oxygen concentration and the flow are adjusted by the double flowmeter.

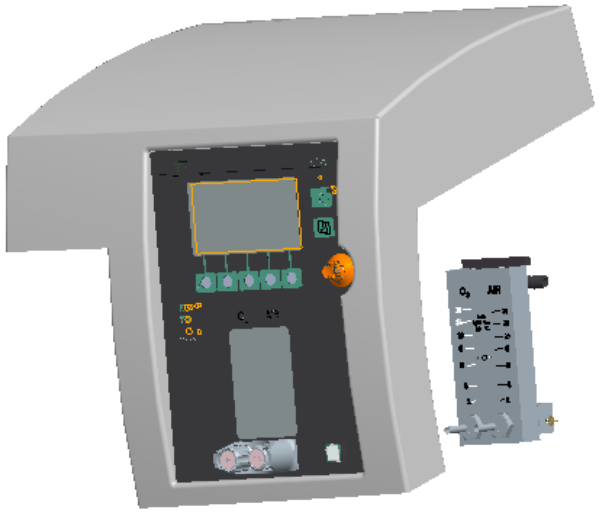

Fig. 21: Double flowmeter

This means that the ventilator can be used with just one supply gas respectively with the internal compressor.

The output pressure is 300 mbar.

The external gas supply is provided by the coded "NIST" resp. "DIN" gas inputs for O_2 and AIR.

The gases must be dry and free of oil and dust.

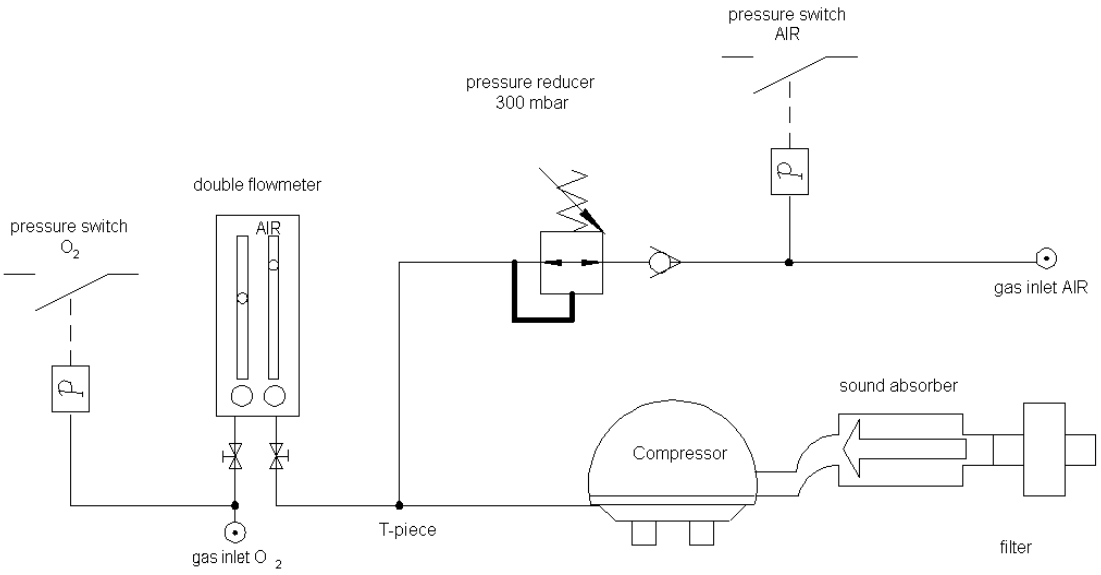

Fig. 22: Overview gas supply

3.3.1 Oxygen supply

The oxygen is conveyed to the double flowmeter through the gas input fitting. If the input pressure is ≥ 1 bar, the oxygen failure alarm is automatically activated.

After the ventilator has been switched on, the pressure of the oxygen input is checked. The corresponding pressure switch is queried by the sensor board.

If there is no pressure (<1 bar), the display shows the question "Is O2 available?".

Confirmation with "NO" deactivates the oxygen failure alarm!

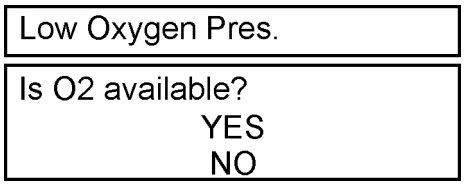

Fig. 23: Display O2 available

3.3.2 Compressed air supply

The compressed air (AIR) is conveyed to the double flowmeter through the gas input fitting,

Pressure is constantly checked at the compressed air input. The corresponding pressure switch is queried by the Power Distribution Unit PDU.

The downstream pressure reducer reduces the pressure to approx. 300 mbar. The non-return valve closes the gas input while the compressor is running.

A T-piece connects the output of the pressure reducer and the compressor with the double flowmeter.

Compressor

If no external compressed air supply is available (input pressure <1 bar), the compressor is automatically switched on.

The PDU board controls the compressor switching on and off.

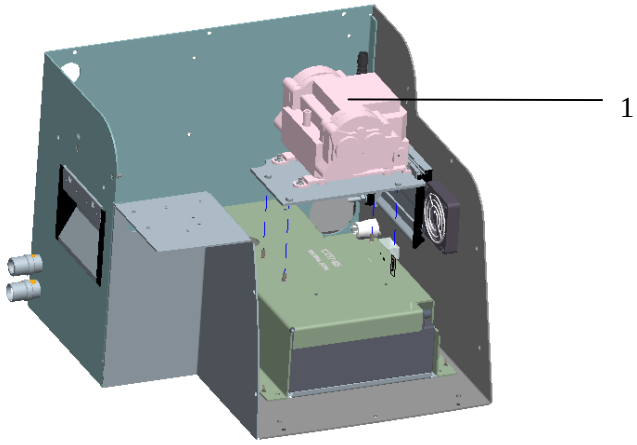

Fig. 24: Compressor

1 compressor

The compressor is a maintenance-free magnetic piston pump.

The compressor runs on mains voltage.

The operating voltage for the compressor is generated by the inverter. This guarantees operation even without the mains power supply.

Operating pressure :	0.3 bar
Delivery volume:	30 l/min
Rated voltage :	230 V 50 Hz
Power consumption:	27 W
Max. switching-on time:	continuous operation

The compressor has a service life of 10,000 hours.

The intake (bacteria) filter is located behind the service flap of the ventilator.

The downstream silencer reduces the noise level to less than 45 dB(A).

3.4 Fresh gas reservoir

The housing of the fresh gas reservoir consists of transparent plastic. The bellows in the inside absorbs the fresh gas during the expiration phase in the semi-open system. The tension springs in the bellows define the compliance of the system.

The springs consist of stainless steel.

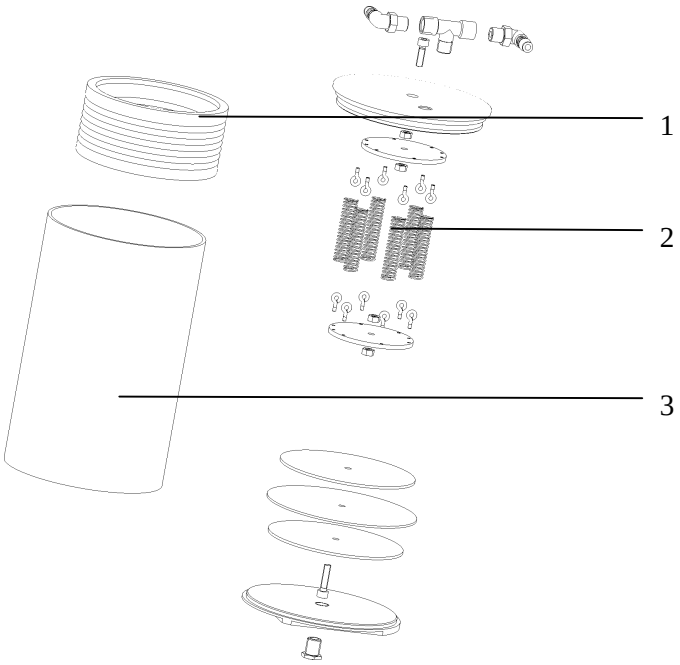

Fig. 25: Fresh gas reservoir

1 bellow
2 spring
3 container

The fresh gas reservoir is only active in the semi-open mode.

It is bypassed in the open mode.

The opening at the bottom of the plastic container conveys the fresh gas out of the unit in the case of damage to the bellows.

Filling and emptying the bellows is controlled by solenoids on the valve block, depending on the set ventilation parameters.

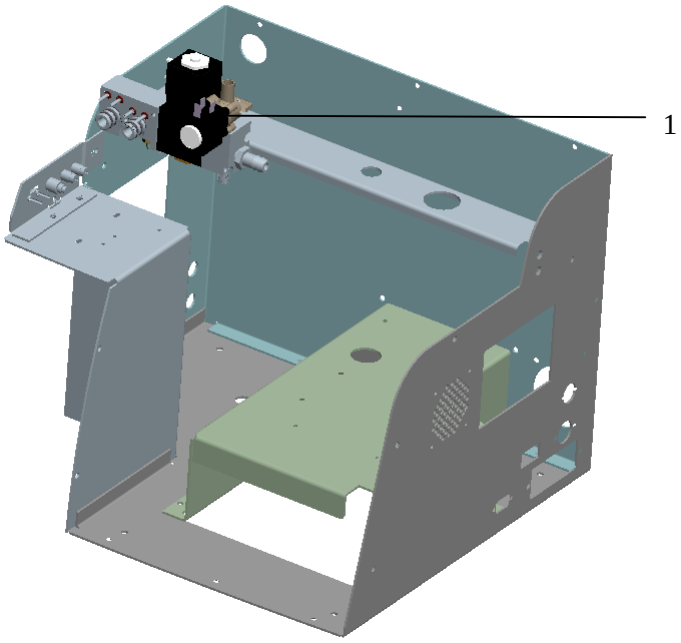

Fig. 26: Valve block

1 valve block

Valve block The valve block accommodates solenoids V1 and V2 and connects them with the connection fitting for the patient part.

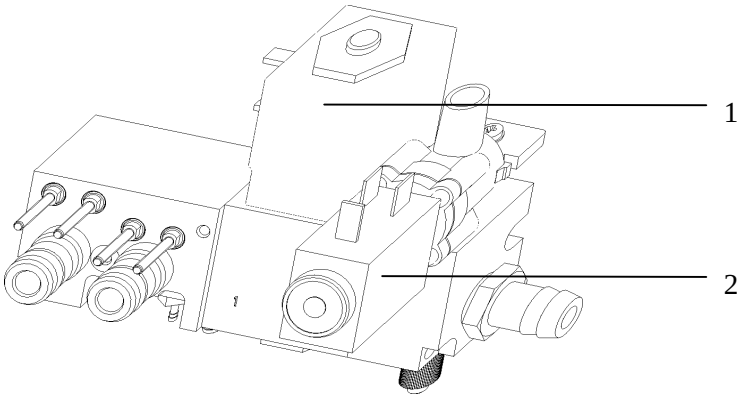

Fig. 27: Valve block

1 solenoid V1 2 solenoid V2

In the open mode (constant flow), the fresh gas reservoir has no function.

Solenoid V2 remains closed permanently.

Solenoid V1 remains open permanently.

There is a constant flow of fresh gas to the patient part.

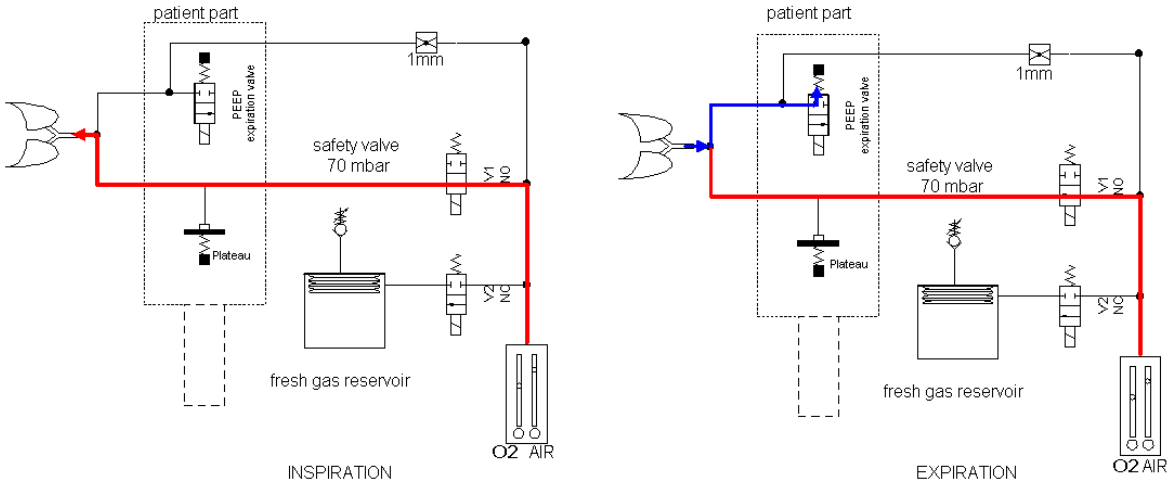

Fig. 28: Gas flow in open mode

In the semi-open mode (constant volume), solenoid V2 remains open permanently.

During the expiration phase, solenoid V1 remains closed. The bellows fills with the constant flow of fresh gas.

During the following inspiration phase, solenoid V1 opens. The collected fresh gas is conveyed by solenoid V1 to the patient.

The tension spring of the bellows ensures that the reservoir empties quickly.

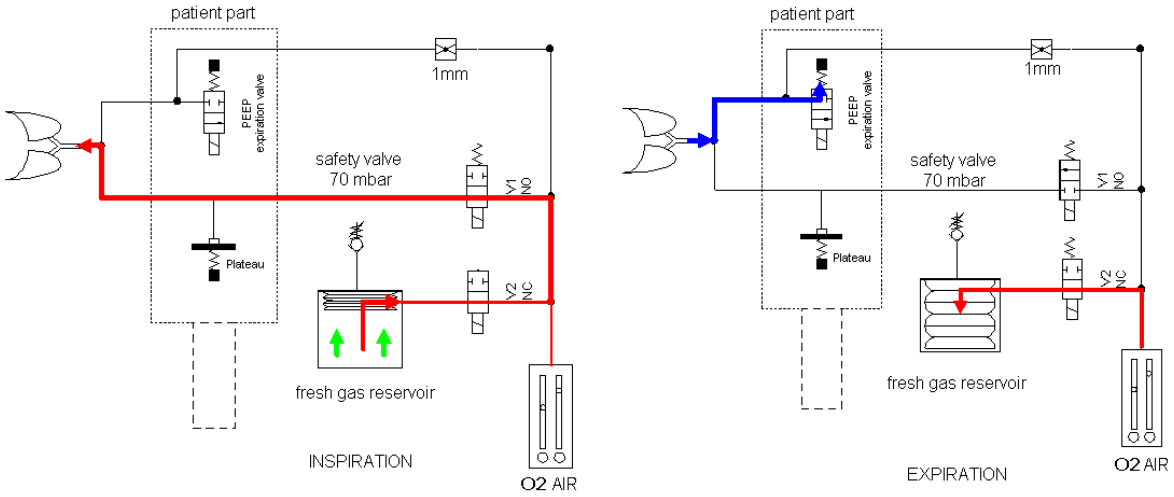

Fig. 29: Gas flow in semi-open mode

The safety valve in the rear wall of the basic housing prevents any overpressure from accumulating in the bellows.

The safety valve opens at a pressure of 70 mbar.

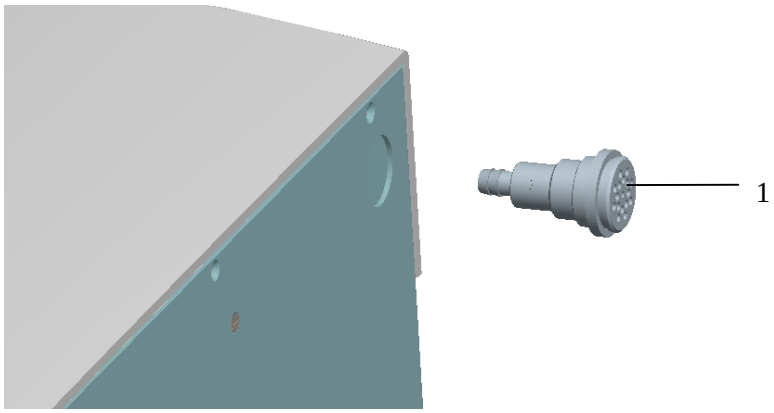

Fig. 30: Safety valve

1 safety valve

The electrical connections for the expiration valve (PEEP valve) and the heating of the humidifier chamber are integrated in the valve block.

A "mini-ISO" plug provides the electrical connection to the patient part.

3.5 Patient part

The patient part contains the pneumatic components of the patient circuit.

The plateau valve limits the maximum pressure and the PEEP valve adjusts the final expiration pressure. The heating and the water bath condition the breathing gas.

Fig. 31: Patient part

1 patient part

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3.5.1 PEEP valve

The PEEP valve consists of a valve plate on an axis. The magnetic core at the end of the axis is wound up by a magnetic coil.

The electric resistance of the coil is approx. 120 Ω.

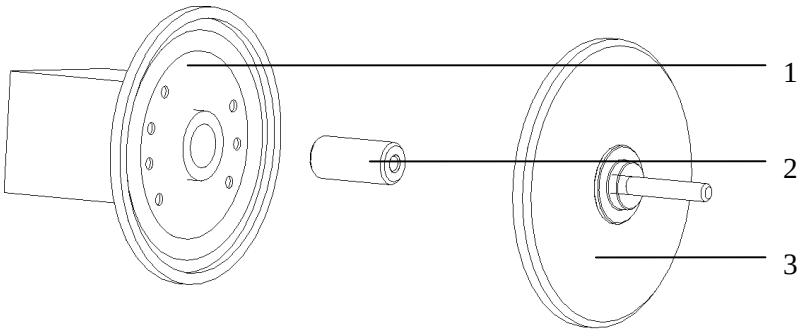

Fig. 32: PEEP valve

1 magnetic coil
2 magnetic core
3 valve disc

During the inspiration phase, the magnetic core is activated by the controller board. The membrane at the magnetic core closes the expiration fitting.

The PEEP valve is open in idle state.

The extent of the final expiration pressure is defined by the tension of the spring before the valve plate. The tension in the spring is adjusted by the PEEP knob.

3.5.2 Plateau valve

The plateau valve consists of a valve plate with a spring before the valve plate which limits the pressure in the patient tube system.

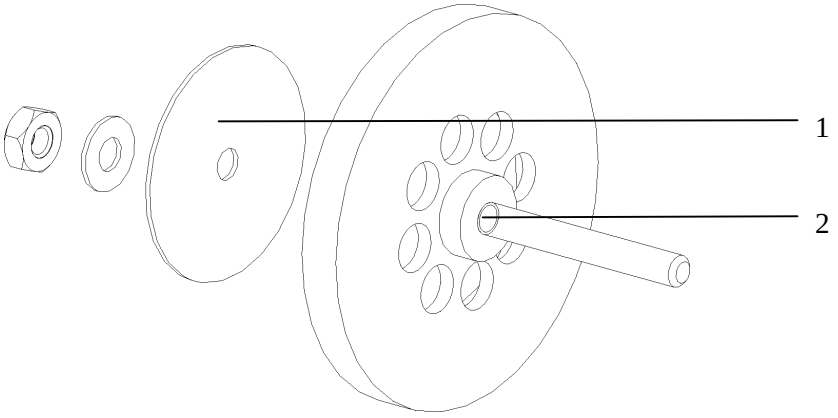

Fig. 33: Plateau valve

1 RLNA valve

2 plateau valve disc

The tension in the spring and thus the maximum pressure is adjusted by the plateau knob.

RLNA valve

The valve plate contains the room air emergency breathing valve.

The silicone disk allows the patient to breathe spontaneously even if the breathing gas should fail.

The negative pressure to be produced by the patient to open the "RLNA" valve is approx. – 4 cmH_2O.

3.5.3 Breathing gas humidifier

Heating and moistening the breathing gas is coordinated by the sensor board. A temperature sensor in the inspiration fitting and at the end of the heating section of the inspiration tube provide the actual temperature value.

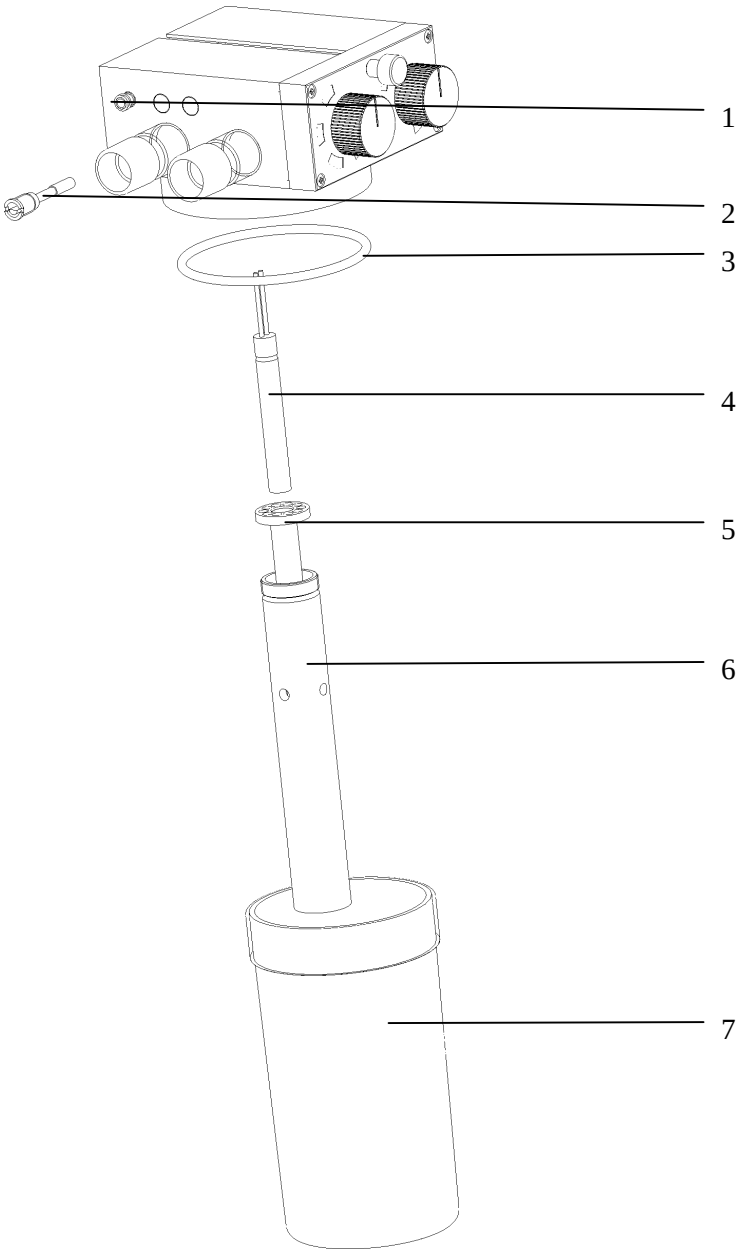

Fig. 34: Patient part humidifer and sensor

1	refilling valve	5	heater tube
2	temperature sensor	6	teflon tube
3	o-ring	7	humidifier chamber
4	heating cartridge		

The sensor board switches the 12V/35W heating cartridge and the tube heating on or off depending on the nominal and actual temperature value.

The electrical resistance of the heating cartridge is 27.5 Ω.

The water of the humidifer chamber evaporates along the heating tube.

The capacity of humidifer chamber is 500 ml

Caution

The surface of the heating cartridge heats up to more than 100 °C!

Do not touch the heating cartridge when the device is switched on!

The moistened, heated breathing air is conveyed into the patient tube system via the inspiration fitting. The heating integrated in the tube system prevents the water from condensing in the tube.

3.6 Patient tube system

Two different patient tube systems are to be used with the **ALIA** ventilator depending on the patient.

The tube systems named here are made of silicone and are therefore considered to be **"FREE OF LATEX AND PVC".**

The tube systems named here can be reused and sterilized using conventional methods!

Please comply with chapter 8 of the **ALIA** operating instructions!

3.6.1 Patient tube system for adults

The patient tube system for adults consists of a Y-piece and a heated 22 mm inspiration and expiration tube.

The colour of the tube fitting for the inspiration tube is red.

It must be connected to the red tube fitting on the patient part.

The neutral coloured expiration tube is connected to the neutral coloured tube fitting.

The continuously heated tube is 1100 mm long.

The electrical resistance of the tube heating is 26 Ω.

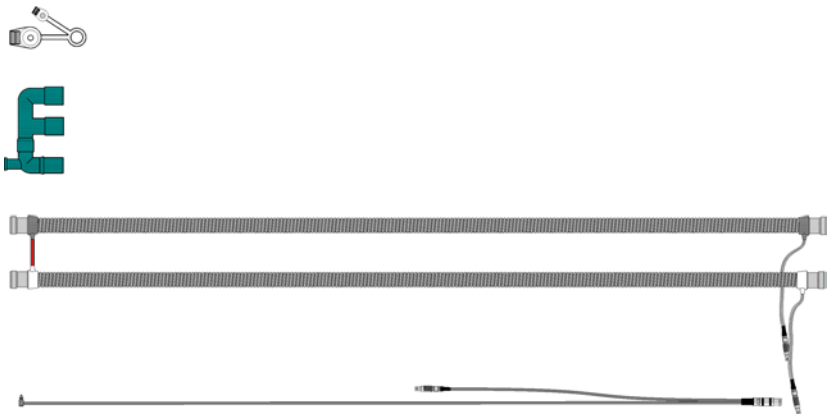

Fig. 35: Tube system for adults

At the patient's end of the inspiration tube, the temperature sensor for controlling the tube temperature is inserted in the tube fitting.

The patient tube system can only be operated with temperature sensor, because otherwise the opening for the sensor would prevent any build up of pressure!

The connectors for the heating are plugged into the corresponding sockets on the ventilator.

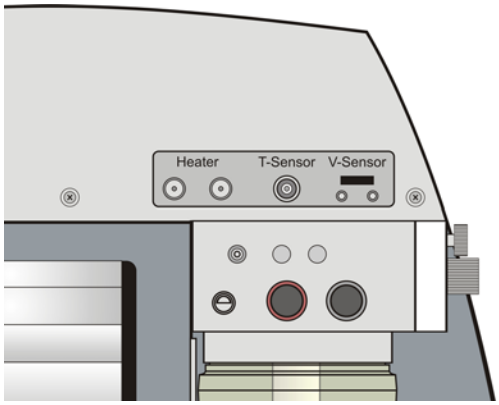

Fig. 36: Heating connection

To measure the inspired or expired flow, a pneumotachograph type D make F. STEPHAN GMBH must be used together with a patient tube system for adults.

3.6.2 Patient tube system for children

The patient tube system for adults consists of a Y-piece and a heated 10 mm inspiration and expiration tube.

The colour of the tube fitting for the inspiration tube is red.

It must be connected to the red tube fitting on the patient part.

The neutral coloured expiration tube is connected to the neutral coloured tube fitting.

The tube is 1200 mm long, 800 mm of which are heated.

The electrical resistance of the tube heating is 26 Ω.

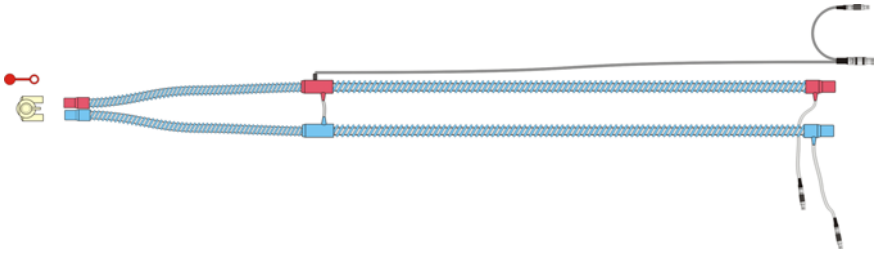

Fig. 37: Tube system for children

At the patient's end of the inspiration tube, the temperature sensor for controlling the tube temperature is inserted in the tube fitting.

The patient tube system can only be operated with temperature sensor, because otherwise the opening for the sensor would prevent any build up of pressure!

The connectors for the heating are plugged into the corresponding sockets on the ventilator.

To measure the inspired or expired flow, a pneumotachograph type C make F. STEPHAN GMBH must be used together with a patient tube system for children.

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3.6.3 Temperature sensor for patient tube system

The temperature sensor measures the temperature of the breathing gas near to the temperature and constitutes the target parameter for controlling the heating.

Fig. 38: Temperature sensor

The resistance of the thermistor bead integrated in the measuring tip decreases with increasing temperature.

Temperature [°C]	Resistance [kΩ]
15	7,855
20	6,246
25	5,000
30	4,028
35	3,265

Table 1: Resistance of the temperature sensor

Caution

The temperature sensor cannot be autoclaved!

The high temperature causes cracks in the measuring bead insulation. Penetrating water can cause short circuits in the sensor and possibly damage the heating control!

Please comply with chapter 8 of the **ALIA** operating instructions!

A specially screened cable with a 5-pin "LEMOSA" plug connects the temperature sensor to the ventilator.

This plug also connects the temperature sensor of the breathing gas humidifier to the ventilator.

3.6.4 Pneumotachograph type D

The pneumotachograph type D measures the inspired and expired flow (> 25 l/min) and is used together with a patient tube system for adults.

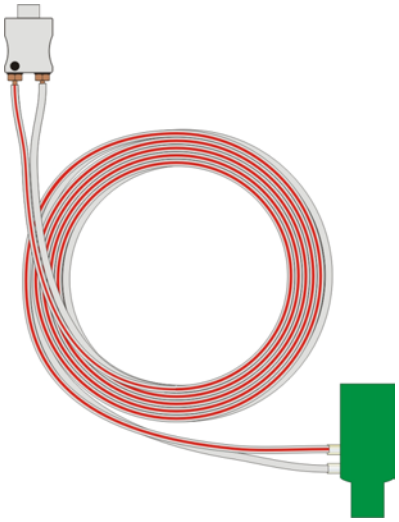

Fig. 39: PNT D

3.6.5 Pneumotachograph Typ C

The pneumotachograph type C measures the inspired and expired flow (> 25 l/min) and is used together with a patient tube system for children.

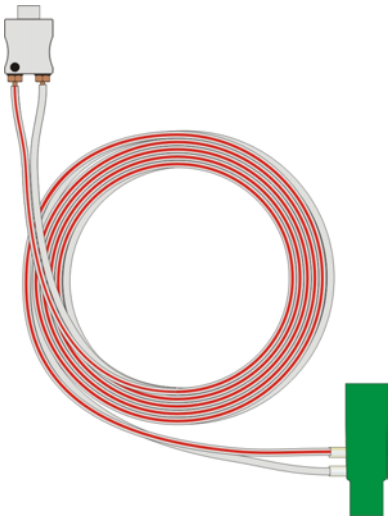

Fig. 40: PNT C

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4 Serial interface

The **ALIA** ventilator is equipped with a serial service and production interface.

The device can be calibrated or subjected to fault analysis. To this end, it must be possible to connect the ventilator to a PC with terminal program.

A NULL modem cable is used for this purpose.

For communication with the ventilator, the PC interface must be configured as follows:

Baud rate:	19200
Data bits:	8
Parity:	none
Stop bits:	1
Flow control:	none

After the ventilator has been switched on, the interface sends the following initialization sequence:

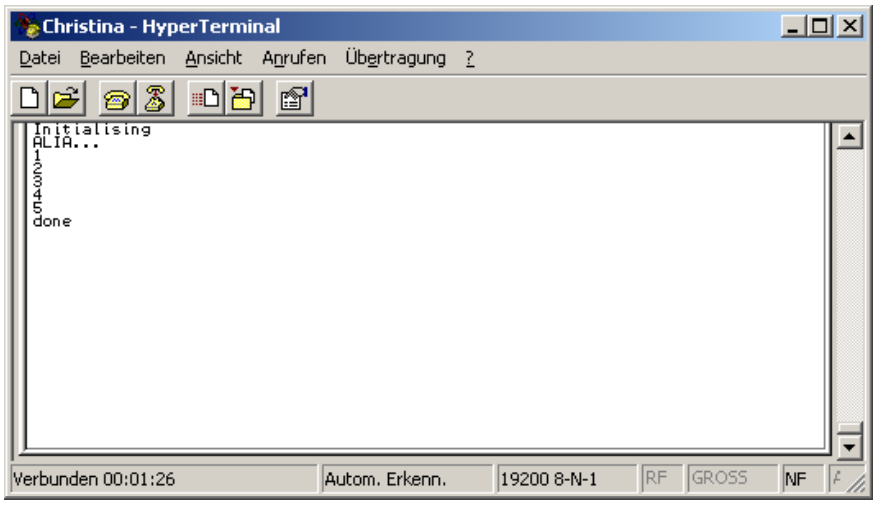

Fig. 41: Initialization sequence

During this phase, the controller runs through the stipulated algorithms for the self-test.

The test run finishes with the output "done". Now various actions can be carried out by entering certain commands:

Caution

There is no complete syntax check of the entered commands. The user must enter the commands correctly.

Incorrect entries can cause damage to the device!

Inputs such as "h" or "help" produce the same results by entering the first letter "h": in this case, output consists of the version number and the list of available commands.

4.1 Commands

cf Input of "cf" –ENTER starts manual offset calibration of the differential pressure sensor:

cf
Start calibration FlowCal=1 PO2Cal=0 PPatCal=0 PRedCal=0

cpr0 Input of "cpr0" –ENTER starts offset calibration of the redundant pressure sensor:

cpr0
Start calibration FlowCal=0 PO2Cal=0 PPatCal=0 PRedCal=30

cpp0 Input of "cpp0" –ENTER starts offset calibration of the pressure sensor near the patient:

cpp0
Start calibration FlowCal=0 PO2Cal=0 PPatCal=30 PRedCal=0

cpr5 Input of "cpr5" –ENTER starts 50 mbar calibration of the redundant pressure sensor:

cpr5
Start calibration FlowCal=0 PO2Cal=0 PPatCal=0 PRedCal=35

cpp5 Input of "cpp5" –ENTER starts 50 mbar calibration of the pressure sensor near the patient:

cpp5
Start calibration FlowCal=0 PO2Cal=0 PPatCal=35 PRedCal=0

Caution

The new values must be saved after calibration!

To this end, adjust YES for the SAVE SETs option in the **ALIA** menu.

The new calibration values are only accepted after confirmation by pressing the IGR!

Saving the values is confirmed on leaving the "Options" menu with the output:

PCal set

4.2 Setting and querying the date and time

Input of "td" –ENTER starts the output of date and time

td
Date 15:11:22 8.12.05

Input of "td_HH:MM:SS_DD:MM:YY" –ENTER readjusts the time and date:

ts 15:17:30 10.12.05

The system is set to 10 December 2005, 15.17 hrs and 30 seconds.

The clock in the **ALIA** ventilator is not buffered!

It serves merely for time recording when saving interface outputs.

4.3 Output of measured values

The output function "out"-ENTER can be used for direct reading of the current IO values of the **ALIA** ventilator. These values are shown in the sections INTADC, EXTADC, CTRLREG and Vimage with additional abbreviations. These act as interpretation help.

These input values are used as the basis for calculations which are shown in the last section, broken down according to pressure, flow, O_2 and temperature.

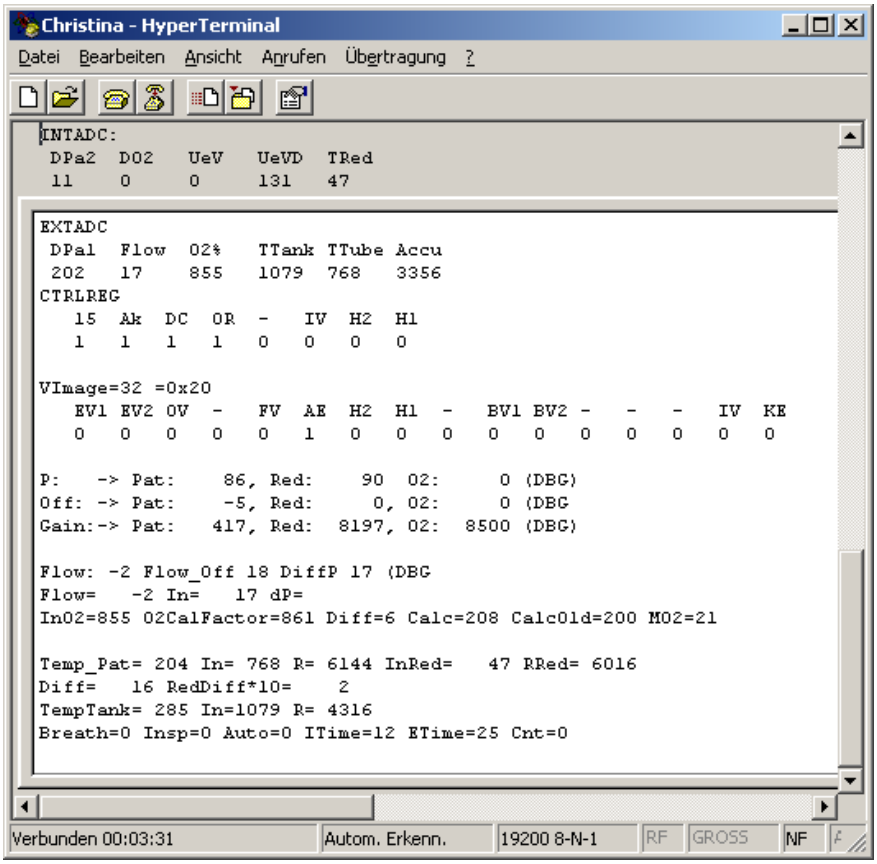
Christina - HyperTerminal
Datei Bearbeiten Ansicht Anrufen Übertragung ?
INTADC:
DPa2 DO2 UeV UeVD TRed
11 0 0 131 47
EXTADC
DPal Flow 02% TTank TTube Accu
202 17 855 1079 768 3356
CTRLREG
15 Ak DC OR - IV H2 H1
1 1 1 1 0 0 0 0
VImage=32 =0x20
EV1 EV2 OV - FV AE H2 H1 - BV1 BV2 - - - IV KE
0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0
P: -> Pat: 86, Red: 90 02: 0 (DBG)
Off: -> Pat: -5, Red: 0, 02: 0 (DBG
Gain:-> Pat: 417, Red: 8197, 02: 8500 (DBG)
Flow: -2 Flow_Off 18 DiffP 17 (DBG
Flow= -2 In= 17 dP=
In02=855 02CalFactor=861 Diff=6 Calc=208 Calc0ld=200 M02=21
Temp_Pat= 204 In= 768 R= 6144 InRed= 47 RRed= 6016
Diff= 16 RedDiff*10= 2
TempTank= 285 In=1079 R= 4316
Breath=0 Insp=0 Auto=0 ITime=12 ETime=25 Cnt=0
Verbunden 00:03:31
Autom. Erkenn.
19200 8-N-1
RF
GROSS
NF

Fig. 42: Output function "out"

INTADC INTADC stands for the output values of the AD converter in the controller board.

DPa2	= Digital value of the redundant patient pressure sensor
DO2	= Monitoring the oxygen pressure switch
UeV	= Measuring the valve flows
UeVD	= Measuring the power supply of the pressure sensors
TRed	= Digital value of the redundant temperature sensor

EXTADC EXTADC stands for the output values of the AD converter in the sensor board.

DPa1	= Digital value of the patient pressure sensor
Flow	= Digital value of the differential pressure in the flow sensor
O2%	= Digital value of the voltage in the oxygen sensor
TTank	= Digital value of the resistance in the temperature sensor of the humidifer chamber
TTube	= Digital value of the resistance of the temperature sensor near to the patient
Accu	= Digital value of the voltage in the rechargeable battery

CTRLREG The register CTRLREG shows the status of the internal hardware monitoring as digital signals.

15	= 15 V OK – voltage present
Ak	= Battery OK
DC	= 5 V supply from the power supply OK
OR	= Position of the ON/OFF switch
-	= not addressed
IV	= Expiration valve OK
H2	= Tube heating OK
H1	= Water bath heating OK

VImage The valve image stipulates which valve is ON or OFF.

Every valve combination possible during operation of the ventilator has its own image.

VImage indicates which combination is currently active.

The individual valves and switches are listed in the register shown below:

EV1 EV2	= Expiration valve
OV	= Calibration valve of the oxygen sensor
FV	= Calibration valve of the offset value of the differential pressure
AE	= Battery switched on
H2	= Tube heating ON/OFF

H1	= Water bath heating ON/OFF	
BV1	= Solenoid V1 fresh gas reservoir	
BV2	= Solenoid V2 fresh gas reservoir	
KE	= Compressor ON / OFF	

Pressure	P:	->Pat:	Current respiratory pressure in 1/10 mbar
		->Red	Redundant pressure
		->O2	Oxygen pressure (switch only / no measurement)
	Off:	->Pat:	ADC offset at 0cmH2O, LSB0[0], P
		->Red:	ADC offset at 0cmH2O, LSB0[1], P_Red
		->O2:	
	Gain:	->Pat:	ADC deviation at 50 cmH2O, PGain[0]
		->Red:	ADC deviation at 50 cmH2O, PGain[1]
		->O2:	

Flow	Flow	Flow in 1/10 L/min
	Flow_Off	Offset ascertained at zero flow
	DiffP	Differential pressure in 1/10 µbar

The displayed flow value results from the dP value calculated by means of the differential pressure value Flow**In**(ExtADC).

Temperature Temp_Pat= 148 In= 993 R= 7944 InRed= 255 RRed=32640

TempTank= 303 In= 997 R= 3988

5 Tools and aids

The following tools and aids are required to perform servicing and maintenance work:

Basic tools

- Screwdrivers in various sizes
- Phillips screwdrivers in various sizes
- Wire cutting pliers
- Needle nose pliers
- Stripping pliers
- Set of Allen keys
- Scissors
- Set of open-end wrenches 5.5 – 13mm
- Gaspipe pliers
- Soldering/unsoldering set
- Tube cutter
- Forceps
- Brush

Special tools

- PLCC extraction tool
- PC with terminal program
- NULL model cable
- Test lung for children
- Test lung for adults
- Hot air fan

Lubricants/ auxiliary substances

- Super Lube (silicone-based)
- Berolube (oxygen-resistant grease)
- Loctite (anaerobic adhesive)
- Teflon sealing tape
- Soldering tin
- Unsoldering cord
- Silicone adhesive E41 and E43

Instruments and accessories

- Electronic pressure meter -10 – 100 mbar / tol. ±1 digit
- Oxygen monitor
- Pressure measuring set consisting of injection syringe, silicone tube 3x1.5, Y-piece (small), 3-way cock
- Safety tester as per VDE 0751
- Vernier calliper
- Measuring tape

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6 Checks and maintenance

6.1 Every time before starting the device

The functions of the device must be checked every time before it is started.

Device type:	SN:	Date:	Signature:

WHAT	HOW	NOMINAL	ACT
O_2 spare bottle	Open bottle valve	O_2 pressure O_2 > 70 bar **ALIA** intake pressure 3 – 6 bar If necessary, close bottle valve and fit a full gas bottle.	☐
ZGA gas connection leads	Visual inspection of gas type colour coding. Note any specific inhouse ruling! (from 30.07.2006)	Iso colour code (31.12.2009 latest or neutral colour code / gas type sticker in place? ⇒ O_2 (oxygen) white ⇒ AIR (compressed air) black-and-white	☐ ☐
	Mechanical unmistakeability : angled plug and gas connections	O_2 ⬡ AIR ☐	☐
Double flowmeter	Check tightness ⇒ - close all metering valves Open O_2 metering valve ⇒ Open AIR metering valve ⇒	Suspended bodies in individual measuring tubes must return to zero Flow of min. 30 l/min Flow of min. 30 l/min	☐ ☐ ☐
Power supply/ battery status	Visual inspection mains connection ⇒ ⇒ ⇒ Disconnect mains connection ⇒	Intact, strain relief in place Mains symbol LED lights up "green" Battery symbol LED lights up "green" or "orange" Device continues to operate, alarm "Power supply fail"	☐ ☐ ☐ ☐
Automatic system test	Main switch "ON" ⇒ System test	System test successful	☐
System tightness	Semi open = "No" ⇒ AIR flow = 4 l/min Alarm limits Pmax 10 + 60 cmH_2O Patient part Plateau = 50 mbar PEEP = 3 mbar Respiration mode CMV Insp = 1 s Exp = 4 s Semi open "Yes" ⇒	Monitoring Pmax over 40 cmH_2O Takes approx. 10 s for internal fresh gas reservoir to fill, the monitoring Pmax over 40 cmH_2O	☐ ☐
Inspiration pressure (plateau) Expiration pressure (PEEP)	Close Y-piece ⇒ ⇒	Monitoring Pmax shows adjusted inspiration pressure Monitoring PEEP shows adjusted expiration pressure	☐ ☐
Apnea monitoring	Adjust respiration form C/BKUP ⇒	After 30 s, "Apnea" alarm	☐

Device type:	SN:	Date:	Signature:

WHAT	HOW	NOMINAL	ACT
Monitoring minute volume	Respiration mode CMV lower limit MV to 1 L ⇒	"Low Min. Volume" alarm	☐
Monitoring airway pressure	Respiration mode CMV upper limit Pmax to 40 cmH_2O Plateau 50 mbar Disconnect Y-piece ⇒	"Peak Pressure" alarm, inspiration stops "Low Pressure/Disconnected" alarm	☐ ☐
AMBU bag	Compress manually ⇒ Release ⇒ Close mask cone manually ⇒	Audible and visible air flow out of mask cone Self-filling Bag compresses only slightly	☐ ☐ ☐
Additions			

Table 2: Test list

6.2 Weekly

Depending on the use of the ventilator, the intake filter of the integrated compressor must be checked for soiling weekly, and replaced at the latest after 6 months.

The intake filter is at the back of the device. Open the service flap to remove and replace the intake filter.

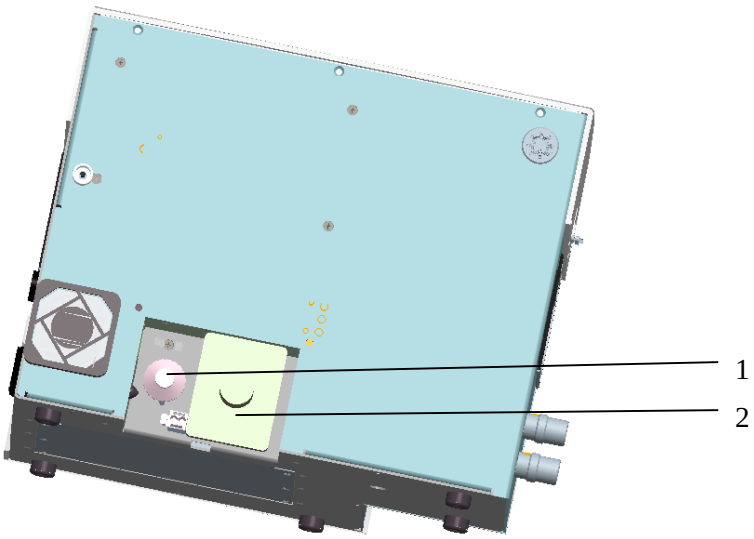

Fig. 43: Back of the **ALIA**: service flap open

1 oxygen sensor 2 intake filter

6.3 ½ yearly

To sustain perfect functioning of the **ALIA** ventilator, maintenance must be carried out at ½ yearly intervals.

This also includes replacement of all wear parts:

6.3.1 ½ yearly maintenance basic unit

O-rings and seals

In the basic **ALIA** device, all O-rings exposed to mechanical load must be replaced every 6 months.

These are the O-rings at the connection fittings of the patient part, the pneumotachograph and the seals of the connection tubes.

It is not compulsory to open the device.

Rechargeable battery

The rechargeable battery used in the **ALIA** ventilator must be checked for sufficient capacity every 6 months.

It must be replaced at the latest every 3 years.

To remove the rechargeable battery, open the flap on the bottom of the ventilator.

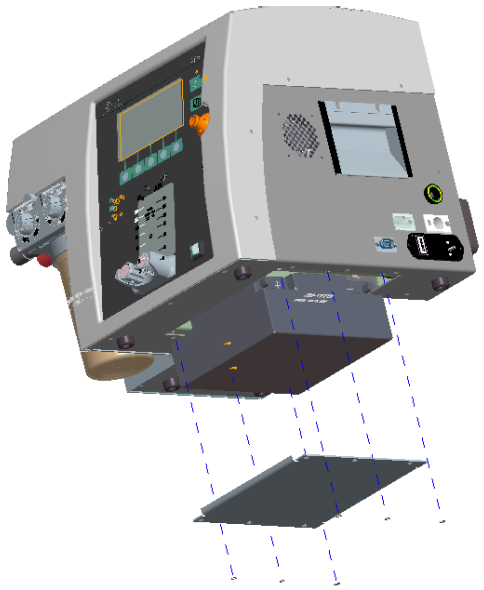

Fig. 44: Battery flap on the bottom of the **ALIA**

Caution

When fitting the new rechargeable battery, take special care to connect it up to the right poles! Incorrect polarity can damage the electronic components.

Oxygen sensor

The service life of the fitted oxygen sensor is approx. 150000 %h.

Check the efficiency of the sensor every six months.

To check the sensor, take it out of the device. Disconnect the connection plug after opening the service flap.

Remove the sensor by unscrewing counter-clockwise.

The basic voltage of the fuel cell can be measured with a multimeter at the plug of the oxygen sensor.

If the measured basic voltage is < 8.5 V, the cell is depleted and must be replaced by a new one.

After opening the packaging, the oxygen sensor takes approx. 20 minutes to achieve its full basic voltage.

Fluctuations in the FiO_2 display are possible during this period.

The oxygen sensor has to be calibrated once it has been fitted in the device and the service flap has been closed.

To do so, set the option O2 Cal to YES in the **ALIA** menu.

Please comply with chapter 3 of the **ALIA** operating instructions!

Caution

The new values must be saved after calibration!

To this end, set the option SAVE SETs to YES in the **ALIA** menu.

The new calibration value is only accepted after leaving the OPTION menu!

Intake filter

Replace the intake filter of the integrated compressor every six months.

Calibrating the pressure sensors

Check calibration of the pressure sensors every six months. Re-calibration is only necessary if the adjusted pressure values deviate by more than 3% from the actually achieved pressure values.

Unscrew the left recessed handle to give access to the calibration block without opening the front housing.

The silicone tube fitted to the 4 mm fitting is connected directly to the two pressure sensors for respiration pressure.

This tube can be used to apply the calibration pressures.

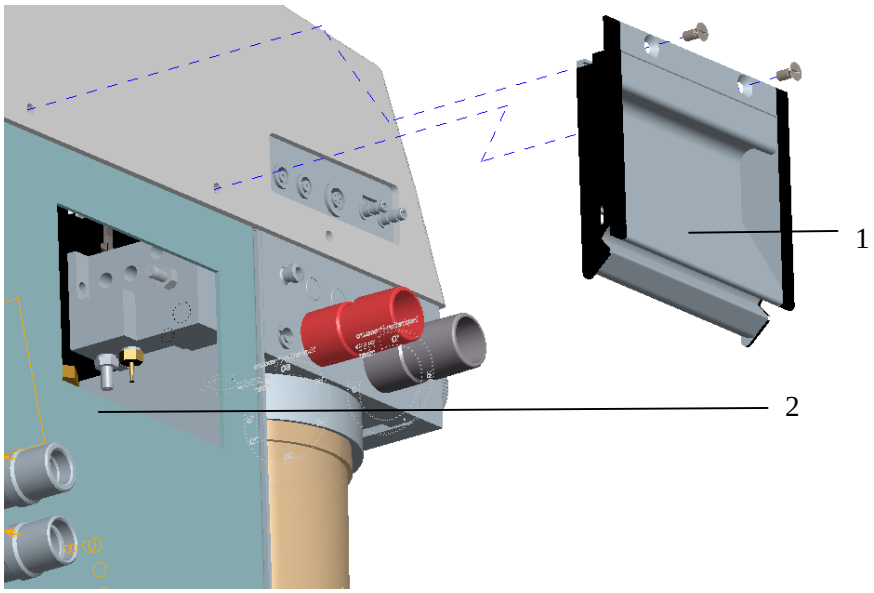

Fig. 45: Tube fitting for pressure calibration

1	handle	2	fitting 4 mm

Use a PC with terminal program for calibration.

Calibration consists of two steps:

1. Offset calibration (calibration the zero point)
2. Calibration at 50 mbar (stipulating the gain P(v)).

1. Offset calibration

To proceed with offset or zero point calibration, apply 0 mbar or atmospheric pressure to both pressure sensors.

To do so, remove the silicone tube from the 4 mm fitting of the calibration block.

Input of "cpr0" –ENTER starts offset calibration of the redundant pressure sensor:

cpr0
Start calibration FlowCal=0 PO2Cal=0 PPatCal=0 PRedCal=30

Input of "cpp0" –ENTER starts offset calibration of the pressure sensor near the patient:

cpp0
Start calibration FlowCal=0 PO2Cal=0 PPatCal=30 PRedCal=0

Caution

The new values for the offset must be saved after calibration!

To this end, set the option SAVE SETs to YES in the **ALIA** menu.

The new calibration value is only accepted after leaving the OPTION menu!

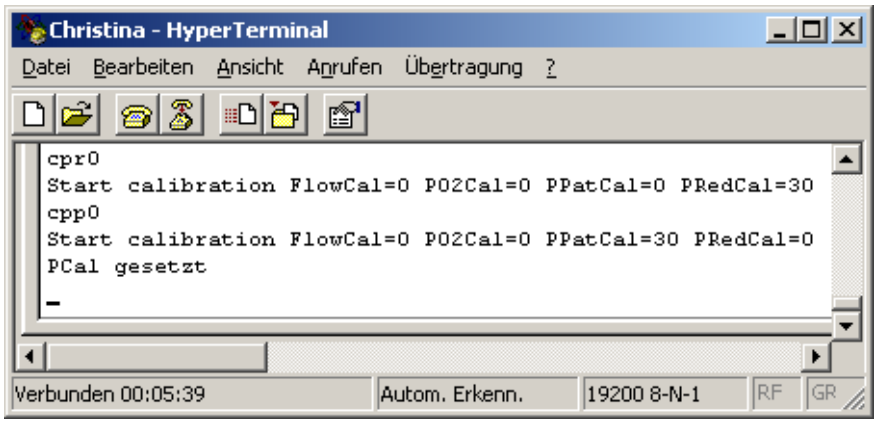

Fig. 46: PC monitor after saving

2. Calibration at 50 mbar

Offset calibration must be carried out before calibration at 50 mbar.

For calibration at 50 mbar, connect the silicone tube at the 4 mm fitting of the calibration block with a cross piece.

Connect the opens to a pressure source and the water column and adjust to 50 mbar.

Input of "cpr5" –ENTER starts 50 mbar calibration of the redundant pressure sensor:

Cpr5
Start calibration FlowCal=0 PO2Cal=0 PPatCal=0 PRedCal=35

Input of "cpp5" –ENTER starts 50 mbar calibration of the pressure sensor near the patient:

Cpp5
Start calibration FlowCal=0 PO2Cal=0 PPatCal=35 PRedCal=0

Caution

The new values must be saved after calibration!

To this end, set the option SAVE SETs to YES in the **ALIA** menu.

The new calibration value is only accepted after leaving the OPTION menu!

6.3.2 Maintenance of the patient part

The inductive resistance in the patient part of the **ALIA** device must be checked with a multimeter at six monthly intervals. The measurement is carried out at the two upper horizontal jacks on the patient part. If the measured resistance is less than 115 Ω or larger than 125 Ω, then the magnetic coil has to be replaced.

Remove the front panel of the patient part every six months. Clean all loose accessible parts with a suitable cleaning agent, e.g. alcohol.

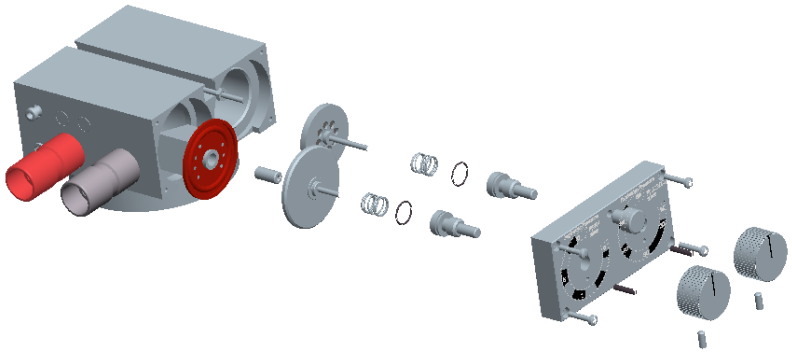

Fig. 47: Remove front panel of patient part

We draw attention particularly to the need for intensive cleaning of the inner part, the coil body and the magnetic core. In the case of pronounced wear (mechanical drive), replace the PEEP valve plate with axis and coil core.

Warning

The magnetic core at the valve axis must be secured with an anaerobic adhesive. The valve must close reliably and not have any contact with the head end of the coil body.

Check that the valve spindles move easily (possibly lubricate with silicone grease). Check that the O-rings of the valve spindles (O-ring 12 x 1) are not damaged; replace if necessary.

When fitting the front panel, ensure that the springs are correctly positioned in the spring spindle guides.

Before tightening the front panel again, check that the patient part functions correctly. Check that the front panel fits correctly according to its outer contour.

Finally, test the patient part with a flow of approx. 5 l and a patient tube system with test lung at the ventilator. Control and readjust the knobs if necessary.

Fit the plate knob in such a way that a pressure of 60 mbar is just reached when the knob is turned right round to the right.

Fit the PEEP knob so that 10 mbar is achieved at the start of the bright section when the knob is turned right round to the right.

6.4 Safety checks

Safety checks must be carried out every six months by F. STEPHAN GMBH or the authorized customer service following the six-monthly maintenance.

6.4.1 Test report

System name: **Alia**
System type: Ventilator
Manufacturer: F. Stephan GmbH

Serial number: _____

Software version: _____
Serial number patient part: _____

PNT: ☐ PNT C SN: _____
☐ PNT D SN: _____

Tube system : ☐ Children
☐ Adults

Test equipment make: Type: Serial number:

_____
_____
_____
_____

Remarks

_____
_____
_____

Tester: _____

Test date: _____

Signature: _____

Visual inspection

Is the system in a perfect visual condition? ☐

Is the nameplate complete and legible? ☐

Is the front panel in perfect condition? ☐

Is the marking (safety nameplate etc.) complete? ☐

Electrical safety test

Test parameter	Criterion	Unit	Result	OK
PE conductor resistance	< 0.,3	Ω		☐
Substitute system leakage current	< 1.0	mA		☐
System leakage current (mains connector turned)	< 0,1	mA		☐

Function test

Sensor calibration (interface)

(only if calibration was carried out !)

Red. sensor ☐ Offset _____
Gain _____

Pat. sensor ☐ Offset _____
Gain _____

Flow sensor ☐ Offset _____

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Power supply

ON/OFF marking on on/off switch		☐
Power on	Alarm: power supply failure (1x)	☐
Front panel LED:	Mains	☐
	Battery	☐
	Vehicle	☐
Power off	Alarm: power supply failure	☐
	Reset after 1 min	☐

O_2 supply

No O_2 supply connected:

Is O2 available?	YES	☐
Alarm "O2 pressure low"		☐
Apply O_2 pressure of 0.9 bar (increase slowly)		☐
Reset alarm "O2 pressure low"		☐

Connect O_2 supply:

Is O2 available?	NO	☐
No alarm "O2 pressure low"		☐
Is O2 available?	YES	☐
No alarm "O2 pressure low"		☐

Performance and leak test

Siemens lung ☐
PNT D ☐
AIR = 25 l/min ☐
SIMV ☐
Insp = 1 s ☐
Exp = 3 s ☐
Semi-open ☐
PEEP = 3 mbar ☐
PLATEAU = 50 mbar ☐

VT (> 650 ml) ☐ _____ ml

Alarm limits Insp = 2 s ☐
Exp = 31 s ☐

Alarm	CMV	**SIMV**	**A/CV**	**C/BKUP**	**ASB**	**N/CPAP**
PEAK PRESS	☐	☐	☐	☐	☐	☐
STENOSIS	☐	☐	☐	☐	☐	-
LOW PRESS/DISCON	☐	☐	☐	☐	☐	-
LOW MIN. VOLUME	☐	☐	☐	☐	☐	-
High MIN. VOLUME	☐	☐	☐	☐	☐	-
VT (EXP) LOW	☐	☐	☐	☐	☐	-
APNOE	☐	☐	☐	☐	☐	-

LED no alarm ☐
HP ☐ Alarm sound HP ☐
MP ☐ Alarm sound MP ☐

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Backup time AIR = 18 l/min ☐

Respiration form	2 s	4 s	8 s	16 s	60 s
C/BKUP	☐	☐	☐	☐	☐
ASB	☐	☐	☐	☐	☐

Trigger
Curve = V' – t ☐
AIR = 18 l/min ☐
Open ☐
Exp = 32 s ☐

Trigger	CMV	SIMV	A/CV	C/BKUP	ASB
2 l/min	☐	☐	☐	☐	☐
6 l/min	☐	☐	☐	☐	☐
1 l/min (no own trigger)	☐	☐	☐	☐	☐

Heating Heating on ☐

Remove temperature sensors
T. SENSOR FAIL HUM ☐
T. SENSOR FAIL PAT ☐
H1 = 0, H2 = 0 ☐

Tube heating
Tube heating HEATING H2 FAIL ☐
Patient part HEATING H1 FAIL ☐

FiO_2 Voltage: ☐ _____ mV
FiO2<18% ☐
LOW FiO2 ☐
HIGH FiO2 ☐
CALIBRATION O2 ☐

Remove O_2 cell O2 SENSOR FAIL ☐

FiO_2	Criterion **± 3 %**	Unit	**Results measuring unit**	**Results Alia**	**OK**
21	20 – 22	%			☐
40	38 – 42	%			☐
60	58 – 62	%			☐
80	77 – 83	%			☐
100	> 97	%			☐

Save settings Save settings ☐

Pressure measurement

PEEP

PEEP	Criterion **± digit**	**Unit**	**Results measuring unit**	**Results Alia**	**OK**
0	> 1	mbar			☐
2	1 – 3	mbar			☐
5	4 – 6	mbar			☐
10	9 – 11	mbar			☐

Pmax

Pmax	Criterion **± digit**	Unit	**Results measuring unit**	**Results Alia**	**OK**
15	14 – 16	mbar			☐
25	24 – 26	mbar			☐
35	34 – 36	mbar			☐

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Pmax	Criterion **± digit**	Unit	**Results measuring unit**	**Results Alia**	**OK**
50	49 – 51	mbar			☐
Max.	Max. ± digit	mbar			☐

Tidal volume

PNT C

VT	Criterion **± 20 %**	Unit	**Results measuring unit**	**Results Alia**	**OK**
50	40 – 60	ml			☐
100	80 – 120	ml			☐

PNT D

VT	Criterion **± 20 %**	Unit	**Results measuring unit**	**Results Alia**	**OK**
50	40 – 60	ml			☐
150	120 – 180	ml			☐
300	240 – 360	ml			☐
500	400 – 600	ml			☐
1000	800 – 1200	ml			☐
1300	1040 – 1560	ml			☐

7 Troubleshooting

Alarm text	Cause	Remedy
O_2 SENSOR FAIL	Faulty calibration Measured sensor voltage outside the measurable range	▪ Calibrate sensor ▪ Check connection lead ▪ Sensor depleted
CALIBRATION O_2	Faulty calibration	▪ Calibrate sensor ▪ Replace sensor
TEMP.SENSOR	Measured temperature close to patient is outside the measurable range	▪ Check temperature sensor ▪ Check sensor cable ▪ Replace temperature sensor

Table 3: Troubleshooting table

8 Annex

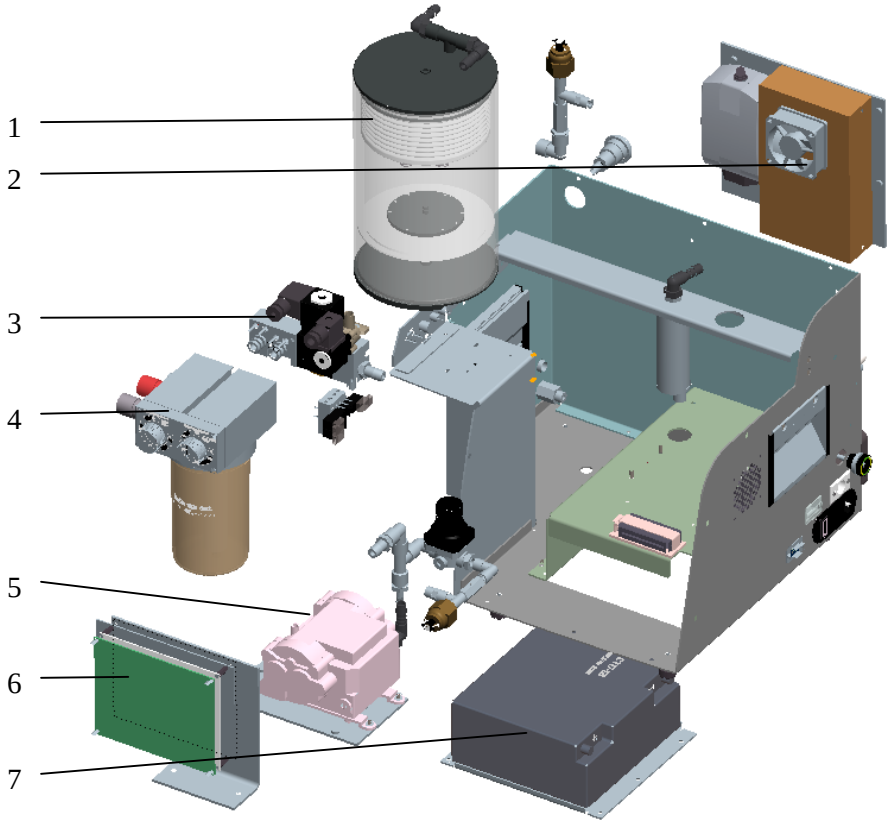
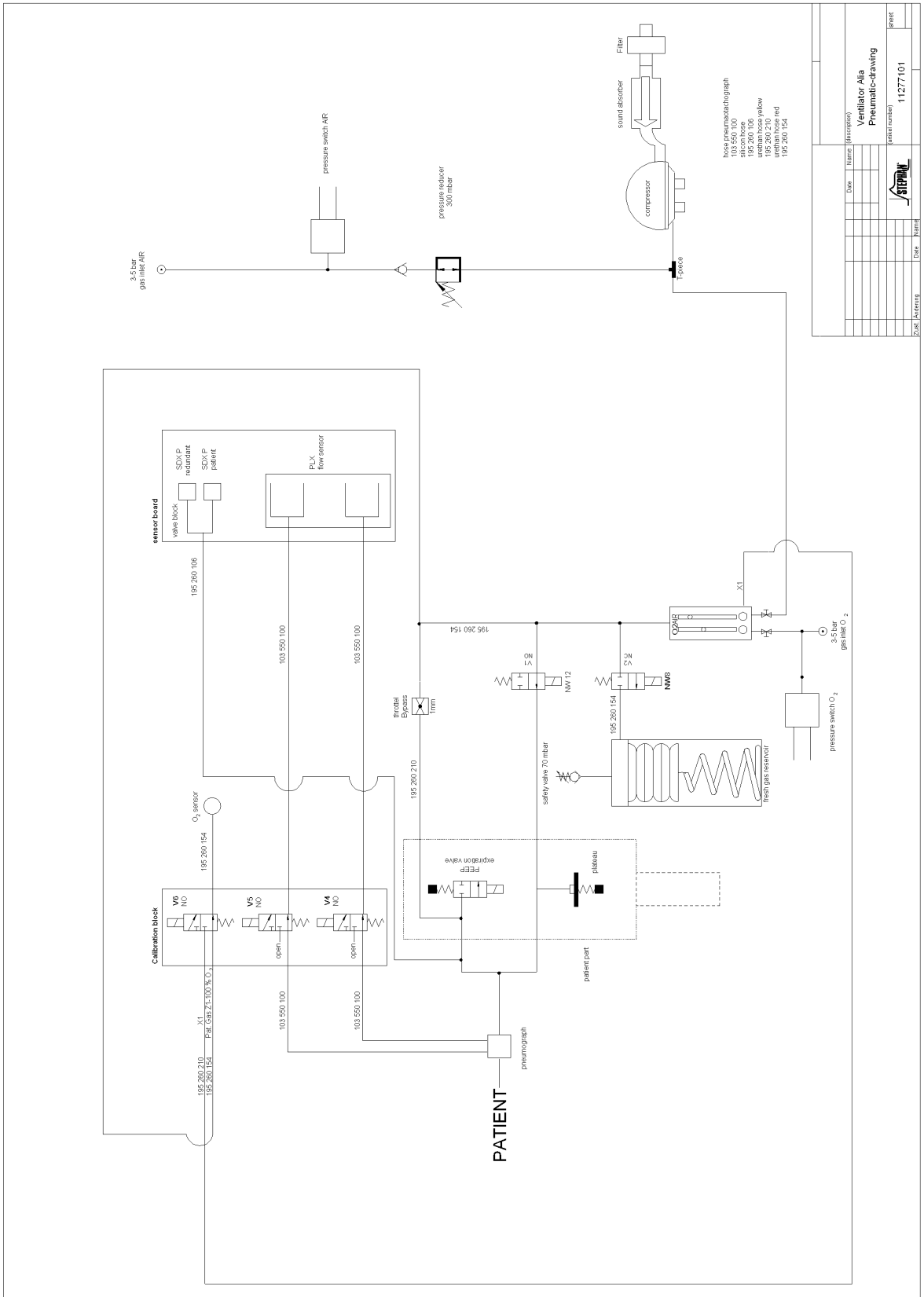


Fig. 48: **ALIA** complete modules

1 fresh gas reservoir
2 power supply
3 valve block
4 patient part
5 compressor
6 sensor and PDU board
7 rechargeable battery



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11 Place for your Notes

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